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Annex to the:

REPORT FROM THE COMMISSION TO THE COUNCIL AND THE EUROPEAN PARLIAMENT

Fifth Report on the Statistics on the Number of Animals used for Experimental and other Scientific Purposes in the Member States of the European Union

{COM (2007) 675 final}

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I. INTRODUCTION

The objective of this report is to present to the Council and the European Parliament, in accordance with Article 26 of Directive 86/609/EEC of 24 November 1986 on the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes¹, the statistical data on the number of animals used for experimental and other scientific purposes in the Member States of the EU.

The first two statistical reports published in 1994² and 1999³ covering data on experimental animals collected in 1991 and 1996 respectively provided a limited amount of statistical analysis due to the absence of a consistent system of reporting the data on the use of experimental animals in the Member States. In 1997 an agreement was reached between the competent authorities of the Member States and the Commission to submit data for the future reports under a format of eight harmonized tables. The third and the fourth statistical reports published in 2003⁴ and 2005⁵ covering data collected in 1999 and 2002 were based on these agreed harmonized tables. This allowed a much wider interpretation of the results on the use of experimental animals in the EU. In spite of the progress made in the content of these two last statistical reports, it ought to be stressed that there were some inconsistencies in the data submitted by the Member States and also that in all cases except the report of 2003, one Member State collected data from another year.

This Fifth Statistical Report covers for the first time data collected by 25 Member States as a result of the accession of 10 new Member States in 2005. It gives an overview of the year 2005 with the exception of one Member State who reported data of 2004.

The Commission Staff Working Document accompanies the "Report from the Commission to the Council and the European Parliament – Fifth Report on the Number of Animals used for Experimental and other Scientific Purposes in the Member States of the European Union". The report summarizes the data and conclusions presented in this Staff Working Document.

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OJ L 358, 18.12.1986, p.1.

² COM (94) 195 final

³ COM (1999) 191 final

COM (2003) 19 final COM (2005) 7 final

II. DATA SUBMITTED AND GENERAL ASSESSMENT

II.1. Data submitted by the Member States

All 25 Member States submitted the data in the agreed EU format.

Regarding the quality of data, in most cases, Member States have applied a quality control check on the set of data submitted for 2005. This exercise was the first for the 10 new Member States (EU 10), and in general the coherence of the data has greatly improved for the other Member States.

The quality check of the data submitted by the Member States is essentially governed by four criteria based on certain relationship between the data in the different tables.

- The first of these relationships is the total number of animals used by species, column
 1.2 of EU Table 1, which is broken down into purposes of experiments in EU Table 2.
 Thus, the totals of the Tables 1 and 2 should be identical.
- The second relationship concerns column 2.6 of EU Table 2 "animals used for toxicological and other safety evaluation" which is broken down into types of products/endpoints, EU Table 3, into Regulatory requirements, EU Table 6, and into types of toxicological tests, EU Table 7. The total at the bottom of column 2.6 must be equal to the total at the bottom of table 3, 6 and 7.
- The third relationship is that the sum of column 2.4 and 2.5 of EU Table 2 must be equal to the total of EU Table 5.
- In the fourth relationship, the total row of EU table 3 "animals used for toxicological and other safety evaluation by types of products" should be equal to the total of table 8.

For the present report it was generally considered that the quality criteria had sufficiently been respected to allow an analysis at European level of all eight EU tables.

II.2. General assessment

Each Member State is requested, pursuant to Articles 13 of Directive 86/609/EEC, to submit to the Commission the statistical data on the animals used for experimental and other scientific purposes. The data covers the year 2005 with the exception of France who reported on the year 2004. Malta has reported no animal use in 2005.

Council Resolution 86/C331/02 of the representatives of the Governments of the Member States of the European Communities, meeting within the Council of 24 November 1986 regarding the protection of animals used for experimental and other scientific purposes allows the use of animals in experiments for education and training, but where the purposes of such experiments are not covered by the Directive i.e. they are not experimental or scientific in the sense of the Directive, Member States will according to the Resolution apply national provisions which are no less severe than those of the Directive. Therefore, a number of Member States have also included animals covered by the Resolution in the report.

⁶ OJ C 331, 23.12.86, p. 2.

The first part of this report aims at providing a comprehensive overview on the numbers of animals used for various experimental purposes in the Community in 2005. The analysis will look at the purposes of the use of animals. Some of these purposes will be broken down further into more precise parameters. It will also look at the different legislative requirements regarding the use of experimental animals and also the type of testing carried out on the different species of animals. For the first time the analysis will cover all eight tables submitted by the Member States in 2005.

Because 10 new Member States are reporting data for the first time it will not be possible to draw conclusions on the evolution of the use of animals for experimental purposed in the EU by comparing data with those of the previous reports. However, some comparisons in trends will be attempted and significant changes in use will be highlighted in the report.

The number of animals used in the 10 new Member States (EU 10) represents 8,6% of the total number of animals used in the 25 Member States (EU 25). Therefore, when any of the categories reported in the different areas show a significant increase or decrease beyond the 8,6%, this will be highlighted in the report

In addition, in the first chapter of this report, Table 1bis with the data of EU 15 and Table 1tris with the data of EU 10 have been prepared to see the effects of the new Member States on the EU statistics. Furthermore, an attempt will be made to compare the results of the total number of animals used in 2005 within the "old" EU 15 with those submitted for the pervious reports.

The second part of this report provides the individual data from the Member States together with their respective comments and interpretations.

In the EU, the total number of animals used for experimental and other scientific purposes in 2005 in the 25 Member States amounts to 12,1 million (with data from France of 2004).

As in previous reports rodents together with rabbits represent almost 78% of the total number of animals used in the EU. Mice are by far the most commonly used species covering 53% of the total use, followed by rats with 19%.

The second most used group of animals was, as in previous years, cold-blooded animals representing 15%. The third biggest group of animals was birds with a little over 5% of the total use.

As in 2002, no Great Apes were used in experiments in the EU in 2005.

II.3. Structure of the Report

The report is divided into two parts:

A A global compilation and overview for the European Union of the statistical data of the Member States for 2005.

A consolidated table has been computed on the basis of the data submitted by the Member States for each EU Table and is presented at the end of each chapter. Each table is illustrated by a graphical presentation to give a more readable overview of the EU situation.

Similarly to what happened in 2002, the complete data for 2005 include statistics from the year 2004 in France. Therefore, the totals used in this report are a mixture of years. Comparisons were nevertheless made on this basis since no other data were available.

The reader is invited to take note that the numbering of tables and graphical presentation in Part A of the report are linked to the numbers of the EU Tables and not to the numbering of the chapters of the report.

B The data submitted by each Member State with a summary of the Member State's comments.

PART A: COMPILATION AND OVERVIEW OF THE DATA OF 2005

III.1. Results of EU Table 1: Species and number of animals

Two types of information can be drawn from the data submitted by the Member States in EU Table 1. The first is relating to the total number of animals used subdivided into 25 species by the Member States. The second is relating to the place of origin of the animals used for experimental or other scientific purposes.

III.1.1. The data on the total number of animals used in the MS

Table 1.1 of this report presents the consolidated data on the number of animals used for experimental purposes, by species, submitted by 25 Member States. Since the previous report of 2002, Table 1.1 includes the data on the number of animals used also in the 10 new Member States

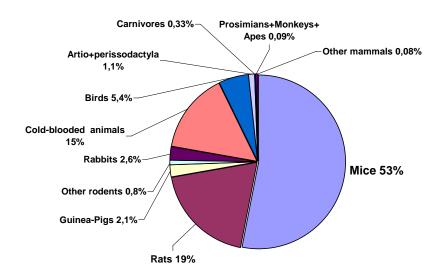
Malta informed the Commission that no animal experiments were carried out in their country in 2005.

The total number of animals used in 2005 (France reporting for 2004) in the 25 Member States (EU 25) amounts to 12.1 million animals. It is important to note that the number of animals used in the 10 new Member States (EU 10) represents 8,6% of the total number of animals in the EU 25. This proportion will be used as the basis to highlight any changes in trends which significantly deviate from it.

III.1.2. Treatment and interpretation of the data of Table 1.1

In order to present an overall evaluation and subsequently a graphical analysis, animals were grouped in classes. The result of this exercise is presented in Table 1.2 at the end of this chapter. Table 1.2 is illustrated by Figure 1.1.

Figure 1.1
Percentages of animals used by classes by the reporting
Member States



Rodents together with rabbits represent 77,5% of the total number of animals used. Within the rodents class, mice (53%) and rats (19%) are by far the most used species.

The second most used group is represented by cold-blooded animals with 15%.

Birds is the next highest animal group being used for experimental purposes with 5,4%

The Artio and Perissodactyla group including horses, donkeys and crossbreeds (Perrisodactyla), pigs, goats, sheep and cattle (Artiodactyla) represent only 1,1% of the total number of animals used in the Member States.

Carnivores represent 0,3% of the total number of animals used and non-human primates represent 0,1% of the animals used in 2005.

III.1.3. Comparison with the data of the previous reports

In this chapter, and the following chapters dealing with comparisons, the reader is invited to take note of the fact that in 1996, in 2002 and 2005 one Member State (France) has reported data respectively for 1997, for 2001 and 2004. Nevertheless, assuming that fluctuations in the annual numbers of animals used per species in a country are limited, it is possible to make semi-quantitative estimates of the observed trends by comparing changes in proportions of use, expressed in percent.

Comparison between proportions of classes of animals used in 1996, 1999 2002 and 2005

Class of species	1996(*)	1999	2002(**)	2005(***)
% Rodents-rabbits	81,3	86,9	78,0	77,5
% Cold-blooded animals	12,9	6,6	15,4	15,
% Birds		4,7	5	5,4
% Artio Perissodactyla		1,2	1,2	1,1

- (*) 14 Member States reporting for 1996, one for 1997
- (**) 14 Member States reporting for 2002, one for 2001
- (***) 24 Member States reporting for 2005, one for 2004

In overall, the percentages of rodents and rabbits show some fluctuation around 80%. For cold-blooded animals the proportion used in 1996, in 2002 and 2005 is between 10 to 15% but a much lower use of 6,6% was observed in 1999.

Birds representing the third largest percentage of animal used, varies between 4 to 5%. The group of artio and perissodactyla fluctuates around 1%.

The inclusion of the data of the new Member States (EU 10) should in principle increase the actual numbers of animals of each species with the magnitude of around 8,6%. However, the use of some species has decreased compared to the 2002 report. This is illustrated in Table 1.0 below.

Three other columns were included in Table 1.0 to show the change between 2002 and 2005 among EU 15, and to further analyse the changes in total numbers. More substantial overall changes have been highlighted and in particular any changes among EU 15 contrary to the overall change.

Table 1.0 : Changes in species number and proportion between 2002 and 2005

Species	Animal numbers in EU 25 2005	Animal numbers in EU 15 2002	Change since 2002	%chan ge since 2002	Animal numbers in EU 15 2005	Change since 2002 in EU 15	%chan ge since 2002 in EU 15
1.a Mice (Mus musculus)	6430346	5459729	970617	17,8	6038846	579117	10,6
1.b Rats (Rattus norvegicus)	2336032	2311344	24688	1,1	2130446	-180898	-7,8
1.c Guinea-Pigs (Cavia porcellus)	257307	226339	30968	13,7	233180	6841	3,0
1.d Hamsters (Mesocricetus)	31535	52382	-20847	-39,8	30935	-21447	-40,9
1.e Other Rodents (other Rodentia)	64474	58827	5647	9,6	47451	-11376	-19,3
1.f Rabbits (Oryctolagus cuniculus)	312681	267675	45006	16,8	293156	25481	9,5
1.g Cats (Felis catus)	3898	3808	90	2,4	3624	-184	-4,8
1.h Dogs (Canis familiaris)	24119	21116	3003	14,2	22010	894	4,2
1.i Ferrets (Mustela putorius furo)	2690	2078	612	29,4	2512	434	20,1
1.j Other Carnivores	8711	3110	5601	180,1	1734	-1376	-44,2
1.k Horses, donkeys and cross breds (Equidae)	5312	4677	635	13,6	4310	-367	-7,8
1.I Pigs (Sus)	66305	61164	5141	8,4	56657	-4507	-7,4
1.m Goats (Capra)	2146	3016	-870	-28,8	1958	-1058	-35,1
1.n Sheep (Ovis)	30021	30979	-958	-3,1	26840	-4139	-13,4
1.o Cattle (Bos)	36271	26569	9702	36,5	21694	-4875	-18,3
1.p Prosimians (Prosimia)	677	1095	-418	-38,2	677	-418	-38,2
1.q New World Monkeys (Ceboidea)	1564	1192	372	31,2	1564	372	31,2
1.r Old World Monkeys (Cercopithecoidea)	8208	8075	133	1,6	8151	76	0,9
1.s Apes (Hominoidea)	0	0	0	0	0	0	0
1.t Other Mammals (other Mammalia)	9950	3618	6332	175,0	4701	1083	29,9
1.u Quail (Coturnix coturnix)	9246	12984	-3738	-28,8	7212	-5772	-44,4
1.v Other birds (other Aves)	649813	521983	127830	24,5	445281	-76702	-14,7
1.w Reptiles (Reptilia)	2477	3168	-691	-21,8	853	-2315	-73,1
1.x Amphibians (Amphibia)	74620	59689	14931	25,0	59402	-287	-0,5
1.y Fish (Pisces)	1749178	1586403	162775	10,3	1627103	40700	2,6
1.z TOTAL	12117583	10731020	1386563	12,9	11070299	339279	3,2

The total number of hamsters, goats, prosimians, quail and reptiles have all decreased from 40% to 22%.

The biggest percentual change has, however, been noted in the increase of the use of other carnivores. This increase is essentially due to the addition of data from the new Member States (see Table 1.0) although these species are not used in great numbers (from 3110 to 8711). This is further contrasted against a decrease in their use in EU 15. The other large increase both in EU 25 and also in EU 15 is for the use of other mammals (3618 to 9950).

One new Member State reported significant use of 'other carnivores', 'other mammals', cattle, 'other rodents', quails and horses, pigs and other birds, in comparison with other Member States. This was attributed to wildlife and environmental research studies in that specific geographical location, and testing in the areas of agricultural and animal breeding specific to that Member State. For further details see section B.

Among the other significant increases in the species used in greater numbers, one should mention the increase in the use of ferrets (29%), of cattle (36%), of other birds (25%) and of

amphibians (25%). These increases, apart from ferrets, are all to be attributed to some of the new Member States.

The use of non-human primates remained as in previous reports at around 0,1% of the total number of animals used. However, by looking at the species, the number of prosimians used decreased by 38% while new world monkeys increased by 31%.

Member States reported that these changes may be attributed to changes in regulatory requirements for pharmaceuticals and in toxicological safety testing.

As in 2002, no great apes were used for experimental or other scientific purposes in 2005.

III.1.4. Comparison with the data of the previous reports for the EU 15

Since the total number of animals includes the data from the 10 new Member States it is not possible to draw a comparison *per se* with the results of the previous reports. However, to allow for some comparisons of trends of the animal use, separate Table 1 bis and 1 tris were drawn. Table 1 bis contains the data of EU 15 and Table 1 tris the data of EU 10 respectively.

In EU 15, the total number of animals used increased in 2005 by 339,279 which represents an increase of 3,1% with regard to 2002.

By examining the data by species, the major increase observed in 2005 is the additional use of about 579,000 mice (10,6%). However this increase of mice is partly compensated by a decrease of the number of rats, hamsters and other rodents used (36%). In 2005 there is also an increase of the number of rabbits used for experimental purposes (9,5%).

Among the other classes of animals, the use of ferrets for carnivores (20,8%) and the use of other mammals (30%) has increased. The changes in the use of non-human primates as explained in chapter III.1.3 are mostly results of changes in EU 15 as only 57 old world monkeys were used in EU 10 in 2005.

On the other hand, the use of all species, within the class of artio and perissodactyla have decreased in comparison to 2002. The same is observed with birds. Finally, one can observe a substantial decrease of 73% in the use of reptiles.

Further breaking down the category 'other', Member States reported use of the following species:

Other rodents: gerbils, old world jerboas (Jaculus jaculus); chinchilla, beaver, ground squirrel, hamsters, aremenio (Cricetulus migratorius) and different species of mice;

Other carnivores: wild-life species used for zoological and ecological studies (e.g. foxes, badgers, seals), otters, fitchew;

Other mammals: boars, bats and shrews, llama, mole, European bison and red deer;

Other birds: mainly coturnix japonica and bob-white quail, poultry species, and zebra finches, canary, parakeet, parrot and farmed avian species for example, (Gallus gallus domesticus)

Table 1.1: Total number of animals used for experimental purposes in the EU Member States

Data of 2005 (*)

Species	ΑT	BE	CY	CZ	DE	DK	EL	ES	EE	FR	HU	ΙE	IT	LV	LT	LU	MT	NL	PL	PT	FI	SI	SK	SE	UK	Totals
1.a. Mice	128634	488125	967	82252	1084358	208375	15340	393217	4350	1510334	138312	17776	534614	10480	5116	3280	0	240048	126492	28318	120636	8556	14975	213727	1052064	6430346
1.b. Rats	11920	106483	0	31703	435417	85664	6024	125754	484	424387	109479	7722	279774	2376	493	720	0	116608	51558	6793	28358	2732	6761	83321	411501	2336032
1.c. Guinea-Pigs	3149	39530	0	4075	37761	5046	574	16780	0	79350	8360	4	11533	297	0	100	0	7479	10763	379	563	38	594	2014	28918	257307
1.d. Hamsters	117	1874	0	220	7916	402	0	908	0	8691	137	0	1537	0	0	0	0	5322	243	129	126	0	0	167	3746	31535
1.e. Other Rodents	107	2260	0	5798	7622	6381	40	294	0	12683	381	0	2303	0	0	0	0	3089	10826	0	3187	18	0	1269	8216	64474
1.f. Rabbits	18439	21159	0	5567	103329	5805	1255	11878	66	93282	9152	379	9916	166	158	20	0	8251	3101	594	1214	533	782	2112	15523	312681
1.g. Cats	12	81	0	29	1023	16	0	168	0	1313	124	119	30	0	0	0	0	334	121	0	0	0	0	220	308	3898
1.h. Dogs	85	1295	0	264	4868	566	14	685	0	5539	1206	167	1064	0	0	0	0	1049	618	36	103	15	6	1166	5373	24119
1.i. Ferrets	0	154	0	159	560	19	0	237	0	155	0	0	0	0	0	0	0	256	19	0	80	0	0	47	1004	2690
1.j. Other Carnivores	0	0	0	7	235	242	0	0	0	0	0	0	0	0	0	0	0	151	6970	0	5	0	0	163	938	8711
1.k. Horses, donkeys and cross breds	71	108	0	314	755	62	1	42	0	223	6	189	63	0	0	0	0	1705	681	8	125	1	0	650	308	5312
1.l. Pigs	818	1876	0	1392	13166	7697	448	4818	0	6587	882	382	2579	0	0	0	0	9853	7358	113	1471	16	0	2722	4127	66305
1.m. Goats	44	157	0	56	275	199	0	119	0	442	2	0	20	0	0	0	0	328	130	4	73	0	0	23	274	2146
1.n. Sheep	195	445	0	720	3517	156	99	821	0	4992	381	601	584	0	0	0	0	2667	2023	290	445	57	0	256	11772	30021
1.o. Cattle	536	944	0	711	2909	489	0	294	0	1296	32	2109	1174	0	0	0	0	4410	13834	45	455	0	0	727	6306	36271
1.p. Prosimians	0	0	0	0	99	0	0	0	0	578	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	677
1.q. N W Monkeys	0	0	0	0	408	0	0	1	0	433	0	0	17	0	0	0	0	50	0	0	0	0	0	12	643	1564
1.r. O W Monkeys	56	449	0	51	1579	0	1	81	0	2778	6	0	395	0	0	0	0	277	0	0	0	0	0	63	2472	8202
1.s . Apes	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
1.t. Other Mammals	0	59	0	188	115	185	0	60	0	0	0	48	68	0	0	0	0	13	5061	1	972	0	0	639	2541	9950
1.u.Quail	14	425	0	30	2457	0	0	1	0	4023	283	0	0	0	0	0	0	152	1470	0	0	0	251	0	140	9246
1.v. Other birds	1011	13266	0	126211	39150	7784	21	8424	0	102240	17151	2024	31697	0	0	0	0	111081	61148	112	5773	22	0	7838	114860	649813
1.w. Reptiles	40	144	0	1475	136	54	0	10	0	0	25	0	378	0	0	0	0	7	121	0	0	3	0	0	84	2477
1.x. Amphibians	865	6177	0	293	10432	840	975	419	0	15675	1709	0	4636	0	0	0	0	3231	13216	51	20	0	0	5496	10585	74620
1.y. Fish	1199	33965	0	69418	64337	35958	901300	30584	0	50397	9581	6420	14584	0	0	0	0	14838	43076	4748	93220	0	0	183049	192504	1749178
1.z. TOTAL	167312	718976	967	330933	1822424	365940	926092	595597	4900	2325398	297209	37940	896966	13319	5767	4120	0	531199	358829	41621	256826	11991	23369	505681	1874207	12117583

^(*) France reporting for 2004

Table 1.1 Bis: Total number of animals used for experimental purposes in the 15 EU Member States reporting before 2005

Data of 2005 (*)

	Species	AT	BE	DE	DK	EL	ES	FR	IE	IT	LU	NL	PT	FI	SE	UK	Totals
1.a.	Mice	128634	488125	1084358	208375	15340	393217	1510334	17776	534614	3280	240048	28318	120636	213727	1052064	6038846
1.b.	Rats	11920	106483	435417	85664	6024	125754	424387	7722	279774	720	116608	6793	28358	83321	411501	2130446
1.c.	Guinea-Pigs	3149	39530	37761	5046	574	16780	79350	4	11533	100	7479	379	563	2014	28918	233180
1.d.	Hamsters	117	1874	7916	402	0	908	8691	0	1537	0	5322	129	126	167	3746	30935
1.e.	Other Rodents	107	2260	7622	6381	40	294	12683	0	2303	0	3089	0	3187	1269	8216	47451
1.f.	Rabbits	18439	21159	103329	5805	1255	11878	93282	379	9916	20	8251	594	1214	2112	15523	293156
1.g.	Cats	12	81	1023	16	0	168	1313	119	30	0	334	0	0	220	308	3624
1.h.	Dogs	85	1295	4868	566	14	685	5539	167	1064	0	1049	36	103	1166	5373	22010
1.i.	Ferrets	0	154	560	19	0	237	155	0	0	0	256	0	80	47	1004	2512
1.j. Carni	Other vores	0	0	235	242	0	0	0	0	0	0	151	0	5	163	938	1734
	lorses, donkeys rossbreeds	71	108	755	62	1	42	223	189	63	0	1705	8	125	650	308	4310
1.l.	Pigs	818	1876	13166	7697	448	4818	6587	382	2579	0	9853	113	1471	2722	4127	56657
1.m.	Goats	44	157	275	199	0	119	442	0	20	0	328	4	73	23	274	1958
1.n.	Sheep	195	445	3517	156	99	821	4992	601	584	0	2667	290	445	256	11772	26840
1.0.	Cattle	536	944	2909	489	0	294	1296	2109	1174	0	4410	45	455	727	6306	21694
1.p.	Prosimians	0	0	99	0	0	0	578	0	0	0	0	0	0	0	0	677
1.q.	N W Monkeys	0	0	408	0	0	1	433	0	17	0	50	0	0	12	643	1564
1.r.	O W Monkeys	56	449	1579	0	1	83	2778	0	395	0	277	0	0	63	2472	8153
1.s.	Apes	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
1.t.	Other Mammals	0	59	115	185	0	60	0	48	68	0	13	1	972	639	2541	4701
1.u.	Quail	14	425	2457	0	0	1	4023	0	0	0	152	0	0	0	140	7212
1.v.	Other birds	1011	13266	39150	7784	21	8424	102240	2024	31697	0	111081	112	5773	7838	114860	445281
1.w.	Reptiles	40	144	136	54	0	10	0	0	378	0	7	0	0	0	84	853
1.x.	Amphibians	865	6177	10432	840	975	419	15675	0	4636	0	3231	51	20	5496	10585	59402
1.y.	Fish	1199	33965	64337	35958	901300	30584	50397	6420	14584	0	14838	4748	93220	183049	192504	1627103
1.z.	TOTAL	167312	718976	1822424	365940	926092	595597	2325398	37940	896966	4120	531199	41621	256826	505681	1874207	11070299

^(*) France reporting for 2004

Table 1.1 Tris: Total number of animals used for experimental purposes in the 10 New EU Member States

Reporting for 2005

Species	CY	CZ	EE	HU	LV	LT	MT	РО	SI	SK	Totals
1.a. Mice (Mus musculus)	967	82252	4350	138312	10480	5116	0	126492	8556	14975	391500
1.b. Rats (Rattus norvegicus)	0	31703	484	109479	2376	493	0	51558	2732	6761	205586
1.c. Guinea-Pigs (Cavia porcellus)	0	4075	0	8360	297	0	0	10763	38	594	24127
1.d. Hamsters (Mesocricetus)	0	220	0	137	0	0	0	243	0	0	600
1.e. Other Rodents (other Rode		5798	0	381	0	0	0	10826	18	0	17023
1.f. Rabbits (Oryctolagus cuniculus)	0	5567	66	9152	166	158	0	3101	533	782	19525
1.g. Cats (Felis catus)	0	29	0	124	0	0	0	121	0	0	274
1.h. Dogs (Canis familiaris)	0	264	0	1206	0	0	0	618	15	6	2109
1.i. Ferrets (Mustela putorius furo)	0	159	0	0	0	0	0	19	0	0	178
1.j. Other Carnivores (other Carnivores)	0	7	0	0	0	0	0	6970	0	0	6977
1.k. Horses, donkeys and crossbred	0	314	0	6	0	0	0	681	1	0	1002
1.I. Pigs (Sus)	0	1392	0	882	0	0	0	7358	16	0	9648
1.m. Goats (Capra)	0	56	0	2	0	0	0	130	0	0	188
1.n. Sheep (Ovis)	0	720	0	381	0	0	0	2023	57	0	3181
1.o. Cattle (Bos)	0	711	0	32	0	0	0	13834	0	0	14577
1.p. Prosimians (Prosimia)	0	0	0	0	0	0	0	0	0	0	0
1.q. New World Monkeys (Ceboidea)	0	0	0	0	0	0	0	0	0	0	0
1.r. Old World Monkeys	0	51	0	6	0	0	0	0	0	0	57
(Cercopithecoidea)											
1.s. Apes (Hominoidea)	0	0	0	0	0	0	0	0	0	0	0
1.t. Other Mammals (other Mammalia)	0	188	0	0	0	0	0	5061	0	0	5249
1.u. Quail (Coturnix coturnix)	0	30	0	283	0	0	0	1470	0	251	2034
1.v. Other birds (other Aves)	0	126211	0	17151	0	0	0	61148	22	0	204532
1.w. Reptiles (Reptilia)	0	1475	0	25	0	0	0	121	3	0	1624
1.x. Amphibians (Amphibia)	0	293	0	1709	0	0	0	13216	0	0	15218
1.y. Fish (Pisces)	0	69418	0	9581	0	0	0	43076	0	0	122075
1.z. TOTAL	967	330933	4900	297209	13319	5767	0	358829	11991	23369	1047284

Table 1.2: Classes of animals used for experimental purposes in the EU Member States Data of 2005 (*)

Species	AT	BE	CY	CZ	DE	DK	EL	ES	EE	FR	HU	ΙE	IT	LV	LT	LU	NL	PL	PT	FI	SI	SK	SE	UK	Totals
Mice	128634	488125	967	82252	1084358	208375	15340	393217	4350	1510334	138312	17776	534614	10480	5116	3280	240048	126492	28318	120636	8556	14975	213727	1052064	6430346
Rats	11920	106483	0	31703	435417	85664	6024	125754	484	424387	109479	7722	279774	2376	493	720	116608	51558	6793	28358	2732	6761	83321	411501	2336032
Guinea-Pigs	3149	39530	0	4075	37761	5046	574	16780	0	79350	8360	4	11533	297	0	100	7479	10763	379	563	38	594	2014	28918	257307
Golden hamsters + other rodents	224	4134	0	6018	15538	6783	40	1202	0	21374	518	0	3840	0	0	0	8411	11069	129	3313	18	0	1436	11962	96009
Rabbits	18439	21159	0	5567	103329	5805	1255	11878	66	93282	9152	379	9916	166	158	20	8251	3101	594	1214	533	782	2112	15523	312681
Cold-blooded animals(1)	2104	40286	0	71186	74905	36852	902275	31013	0	66072	11315	6420	19598	0	0	0	18076	56413	4799	93240	3	0	188545	203173	1826275
birds (2)	1025	13691	0	126241	41607	7784	21	8425	0	106263	17434	2024	31697	0	0	0	111233	62618	112	5773	22	251	7838	115000	659059
Artio+Perissodactyla (3)	1664	3530	0	3193	20622	8603	548	0	0	13540	1303	3281	4420	0	0	0	18963	24026	460	2569	74	0	4378	22787	140055
Carnivores (4)	97	1530	0	459	6686	843	14	1090	0	7007	1330	286	1094	0	0	0	1790	7728	36	188	15	6	1596	7623	39418
Prosimians+monkeys+ apes	56	449	0	51	2086	0	1	84	0	3789	6	0	412	0	0	0	327	0	0	0	0	0	75	3115	10451
Other Mammals	0	59	0	188	115	185	0	60	0	0	0	48	68	0	0	0	13	5061	1	972	0	0	639	2541	9950
Total	167312	718976	967	330933	1822424	365940	926094	595597	4900	2325398	297209	37940	896966	13319	5767	4120	531199	358829	41621	256826	11991	23369	505681	1874207	12117583

Species% total	ΑT	BE	CY	CZ	DE	DK	EL	ES	EE	FR	HU	IE	IT	LV	LT	LU	NL	PL	PT	FI	SI	SK	SE	UK	Mean
Mice	76,88	67,89	100	24,85	59,50	56,94	1,66	66,02	88,78	64,95	46,54	46,85	59,60	78,68	88,71	79,61	45,19	35,25	68,04	46,97	71,35	64,08	42,27	56,13	53,07
Rats	7,12	14,81	0,00	9,58	23,89	23,41	0,65	21,11	9,88	18,25	36,84	20,35	31,19	17,84	8,55	17,48	21,95	14,37	16,32	11,04	22,78	28,93	16,48	21,96	19,28
Guinea-Pigs	1,88	5,50	0,00	1,23	2,07	1,38	0,06	2,82	0,00	3,41	2,81	0,01	1,29	2,23	0,00	2,43	1,41	3,00	0,91	0,22	0,32	2,54	0,40	1,54	2,12
Golden hamsters + other rodents	0,13	0,57	0,00	1,82	0,85	1,85	0,00	0,20	0,00	0,92	0,17	0,00	0,43	0,00	0,00	0,00	1,58	3,08	0,31	1,29	0,15	0,00	0,28	0,64	0,79
Rabbits	11,02	2,94	0,00	1,68	5,67	1,59	0,14	1,99	1,35	4,01	3,08	1,00	1,11	1,25	2,74	0,49	1,55	0,86	1,43	0,47	4,45	3,35	0,42	0,83	2,58
Cold-blooded animals(1)	1,26	5,60	0,00	21,51	4,11	10,07	97,43	5,21	0,00	2,84	3,81	16,92	2,18	0,00	0,00	0,00	3,40	15,72	11,53	36,30	0,03	0,00	37,29	10,84	15,07
birds (2)	0,61	1,90	0,00	38,15	2,28	2,13	0,00	1,41	0,00	4,57	5,87	5,33	3,53	0,00	0,00	0,00	20,94	17,45	0,27	2,25	0,18	1,07	1,55	6,14	5,44
Artio+Perissodactyla (3)	0,99	0,49	0,00	0,96	1,13	2,35	0,06	1,02	0,00	0,58	0,44	8,65	0,49	0,00	0,00	0,00	3,57	6,70	1,11	1,00	0,62	0,00	0,87	1,22	1,16
Carnivores (4)	0,06	0,21	0,00	0,14	0,37	0,23	0,00	0,18	0,00	0,30	0,45	0,75	0,12	0,00	0,00	0,00	0,34	2,15	0,09	0,07	0,13	0,03	0,32	0,41	0,33
Prosimians+monkeys+ apes	0,03	0,06	0,00	0,02	0,11	0,00	0,00	0,01	0,00	0,16	0,00	0,00	0,05	0,00	0,00	0,00	0,06	0,00	0,00	0,00	0,00	0,00	0,01	0,17	0,09
Other Mammals	0,00	0,01	0,00	0,06	0,01	0,05	0,00	0,01	0,00	0,00	0,00	0,13	0,01	0,00	0,00	0,00	0,00	1,41	0,00	0,38	0,00	0,00	0,13	0,14	0,08
Total	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100

Malta has reported 0 animals used in 2005

- (*) (1)
- France reporting for 2004 = Reptiles +amphibians + fish
- = Quails and other birds
- = Horses, donkeys and cross bred + pigs +goats and sheep + cattle = cats + dogs + ferrets + other carnivores

III.2. Results of EU Table 1: Origin of animals used

III.2.1. The data on the origin of the species

The consolidated results of EU Table 1 on the origin of some selected species used for experimental purposes in the 25 Member States are reported in Table 1.3 at the end of this chapter. The consolidated table only indicates species for which the origin must be reported.

In addition, EU Table 1 requires that Member States report the number of animals re-used in experiments.

III.2.2. Treatment and interpretation of the data

The data of column 1.3 and 1.4 of Table 1.3 of this report have been grouped to represent animals coming from the Community.

Figure 1.2 represents the percentage of origin of animals versus the species.

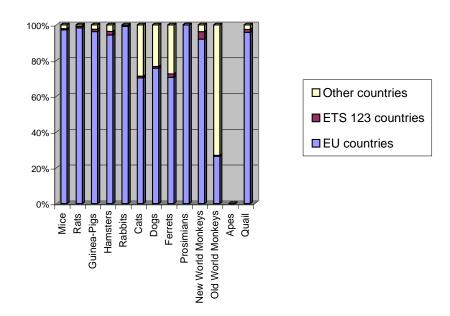


Figure 1.2: Origin of species

The chart shows that the majority of the species originated from the EU countries. However, certain species such as cats, dogs and ferrets and old world monkeys are of non-European origin.

III.2.3. Comparison with data of the previous report

The general pattern on the origin of the species is quite similar to that observed in the previous reports. It should be noted however, that for the first time in 2005 the prosimians

were all of EU origin. A similar trend can also be observed with the new world monkeys where an increasing amount was either of EU or ETS 123 origin at the expense of other countries. Also, old world monkeys coming from EU origins increased. On the other hand the number of cats not of European origin has increased in comparison to the report of 2002.

Table 1.3: Number of animals used in relation to their place of origin

Data of 2005

1.1.Species	1.2. Total	1.3.Animals coming from registered breeding or supplying establishments within the reporting country	1.4. Animals coming from elsewhere in the EC	1.5.Animals coming from Member Countries of the Council of Europe which are parties to the Convention ETS 123 (excluding EC Member States)	1.6.Animals coming from other origins	1.7.Re-used animals
1.a. Mice (Mus musculus)	6430346	5408519	842034	38621	141172	254
1.b. Rats (Rattus norvegicus)	2336032	2002798	294875	17328	21031	118
1.c. Guinea-Pigs (Cavia porcellus)	257307	178363	69291	3245	6408	2
1.d. Hamsters (Mesocricetus)	31535	25276	4448	641	1170	0
1.f. Rabbits (Oryctolagus cuniculus)	312681	294616	15595	839	1631	13488
1.g. Cats (Felis catus)	3898	2251	492	34	1121	1007
1.h. Dogs (Canis familiaris)	24119	15542	2732	220	5625	3763
1.i. Ferrets (Mustela putorius furo)	2690	1662	240	50	738	22
1.p. Prosimians (Prosimia)	677	578	99	0	0	111
1.q. New World Monkeys (Ceboidea)	1564	1244	195	65	60	410
1.r. Old World Monkeys (Cercopithecoidea)	8210	1459	719	38	5994	1740
1.s. Apes (Hominoidea)	0	0	0	0	0	0
1.u. Quail (Coturnix coturnix)	9246	8860	0	152	234	0
1.z. TOTAL	9418305	7941168	1230720	61233	185184	

Note 1 Column 1.5 concerns only those Member countries of the Council of Europe which, at the beginning of the reporting period, are Parties to the

Convention ETS 123. Thus an updated list of those countries has to be used when filling in this column

(Note 2: Only species for which origin has to be reported are included in this table)

Note 3: The number of re-used animals in column 1.7 should be excluded from the total in the column 1.2.

III.3. Results of EU Table 2: Purposes of the experiments

III.3.1. The data on purpose of the experiments

The consolidated data on purposes of the experiments of the 25 Member States are presented in Table 2.1 at the end of this chapter.

III.3.2. Treatment and interpretation of the data

Table 2.2 presents the results of the consolidated data of the purposes of the procedures carried out in the 25 Member States in 2005. In order to facilitate the presentation of results some species and some purposes were grouped.

The percentage of the number of animals used for selected purposes is presented in Figure 2.1.

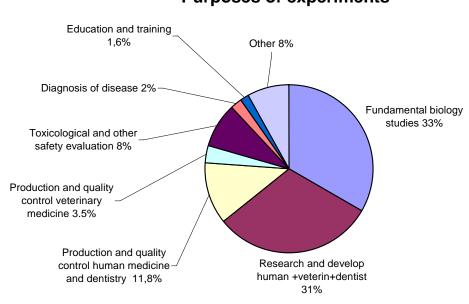


Figure 2.1 Purposes of experiments

As in previous years, more than 60% of animals were used in research and development for human medicine, veterinary medicine, dentistry and in fundamental biology studies.

Production and quality control of products and devices in human medicine, veterinary medicine and dentistry required the use of 15,3% of the total number of animals reported in 2005.

Toxicological and other safety evaluation represents 8% of the total number of animals used for experimental purposes.

III.3.3. Comparison with the data of the previous report

It must be remembered that the comparison is aiming to detect changes in trends rather than drawing formal conclusions. The most significant change that can be identified is the number of animals used for toxicological and other safety evaluation, which has dropped from about 9,9%

(data of 2002) to 8% for the data submitted by 25 Member States for this report. The decrease is also important in total numbers, i.e. from 1,066,047 to 1,026,286 animals while at the same time covering the 10 new Member States.

The percentage of animals used for education and training is also showing a decreasing trend while other purposes seem to indicate an increase. In terms of numbers of animals the decrease ranges from 341,967 to 198,994 and the increase from 597,960 to 984,238 respectively.

The decrease of animals used for education and training can be attributed to both an uptake of alternative techniques and the re-use of animals.

'Other' purposes covers amongst other things virology, immunology for production of monoclonal and polyclonal antibodies, physiology of foetal-maternal interaction in mouse gene transgensis, oncological treatment, pharmaceutical R&D, combined drug testing and genetics.

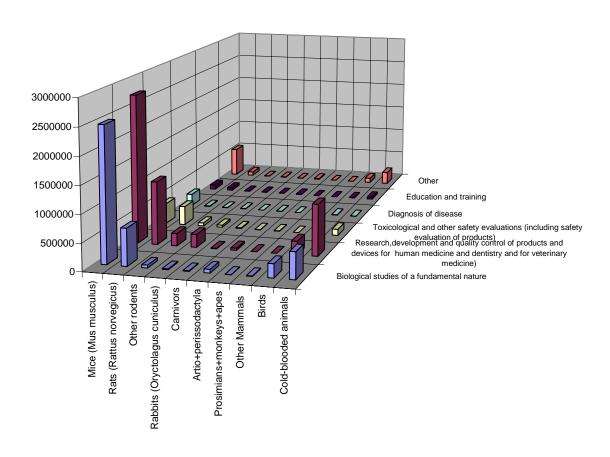
Table 2.2: Number of animals used for selected purposes versus species

Species	Biological studies of a fundament al nature	Research, developm ent and quality control of products and devices for human medicine and dentistry and for veterinary medicine)	Toxicologic al and other safety evaluations (including safety evaluation of products)	Diagnosi s of disease	Education and training	Other	Total
Mice	2465474	2727254	384741	225524	86597	551356	6440946
Rats	677533	1161517	350275	13564	50048	72876	2325813
Other rodents	53241	230403	56006	4512	2606	6548	353316
Rabbits	15463	237411	38761	8322	3856	8829	312642
Carnivores	11605	9309	14884	348	674	2339	39159
Artio+perissodactyla	64419	41079	4542	4100	9491	16341	139972
Prosimians+monkeys+apes	1456	1397	7004	16	42	536	10451
Other mammals	8978	214	15	0	4	739	9950
Birds	251443	249024	53935	9723	5440	89494	659059
Cold-blooded animals	485858	942973	116123	5905	40236	235180	1826275
TOTAL	4035470	5600581	1026286	272014	198994	984238	12117583

Figure 2.2 presents the number of animals used for selected purposes by classes of species.

From Figure 2.2 one can see that the highest amount of use of mice and rats is attributed to fundamental biology and also of research, development and control of products and devices for medicine, dentistry and veterinary medicine. The use of cold-blooded animals is following a similar pattern for different purposes.

Figure 2.2 Species and experimental purposes



EN EN

Table 2.1: Number of animals used in experiments for selected purposes

Purposes versus species

data of 2005*

2.1Species	2.2. Biological studies of a fundamenta I nature	2.3. Research and development of products and devices for human medicine and dentistry and for veterinary medicine (excluding toxicological and other safety evaluations counted in column 2.6)	2.4.Production and quality control of products and devices for human medicine and dentistry	2.5.Production and quality control of products and devices for veterinary medicine	2.6.Toxicological and other safety evaluations (including safety evaluation of products and devices for human medicine and dentistry and for veterinary medicine	2.7.Diagno sis of disease	2.8.Education and training	2.9.Other	2.10.Total
1.a. Mice (Mus musculus)	2465474	1639698	902318	185238	384741	225524	86597	551356	6440946
1.b. Rats (Rattus norvegicus)	677533	920875	209791	30851	350275	13564	50048	72876	2325813
1.c. Guinea-Pigs (Cavia porcellus)	12911	47490	111505	24323	53498	2150	1691	3739	257307
1.d. Hamsters (Mesocricetus)	10716	6167	274	10098	1670	1395	390	825	31535
1.e. Other Rodents (other Rodentia)	29614	30359	0	187	838	967	525	1984	64474
1.f. Rabbits (Oryctolagus cuniculus)	15463	32814	185572	19025	38761	8322	3856	8829	312642
1.g. Cats (Felis catus)	1123	1044	138	687	222	64	129	491	3898
1.h. Dogs (Canis familiaris)	1997	4457	244	1182	14621	243	500	616	23860
1.i. Ferrets (Mustela putorius furo)	510	1299	42	14	41	41	45	698	2690
1.j. Other Carnivores (other Carnivore)	7975	0	0	202	0	0	0	534	8711
1.k. Horses, donkeys and cross breds (Equidae)	1293	472	203	1957	40	182	973	192	5312
1.l. Pigs (Sus)	27052	15159	489	6610	3349	1888	5854	5821	66222
1.m. Goats (Capra)	828	280	84	41	39	214	317	343	2146
1.n. Sheep (Ovis)	10442	2721	5731	1217	457	871	956	7626	30021
1.o. Cattle (Bos)	24804	3691	55	2369	657	945	1391	2359	36271
1.p. Prosimians (Prosimia)	384	0	0	0	97	0	0	196	677
1.q. New World Monkeys (Ceboidea)	357	327	43	0	650	16	5	166	1564
1.r. Old World Monkeys (Cercopithecoidea)	715	654	373	0	6257	0	37	174	8210
1.s. Apes (Hominoidea)	0	0	0	0	0	0	0	0	0
1.t. Other Mammals (other Mammalia)	8978	144	0	70	15	0	4	739	9950
1.u. Quail (Coturnix coturnix)	1722	0	0	0	3191	0	169	3913	8995
1.v. Other birds (other Aves)	249721	104833	12727	131464	50744	9723	5271	85581	650064
1.w. Reptiles (Reptilia)	1646	13	0	0	12	0	774	32	2477
1.x. Amphibians (Amphibia)	55349	253	0	0	542	99	15666	2711	74620
1.y. Fish (Pisces)	428863	933278	280	9149	115569	5806	23796	232437	1749178
1.z. TOTAL	4035470	3746028	1429869	424684	1026286	272014	198994	984238	12117583

(*)France reporting for 2004

III.4. Results of EU Table 3: <u>Toxicological and safety evaluation by type of product/endpoints</u>

III.4.1. The data on toxicological and safety evaluation by type of products/endpoints

The consolidated table giving the number of animals used in toxicological and other safety evaluation of products (EU Table 3) in 25 Member States is presented in Table 3.1 at the end of this chapter.

The percentage of the number of animals used for different types of product is presented in Figure 3.1.

III.4.2. Treatment and interpretation of the data

3.9 Potential or actual contaminents in the general 3.10 Other toxicological or environment which do not safety evaluations appear in other columns 3.8 Products/ substances 8.3% used or intended to be used mainly as additives in food for animal consumption 3,3% 3.7 Products/ substances 3.2 Products/ substances used or intended to be used or devices for human mainly as additives in food medicine and dentistry and for human consumption for veterinary medicine 0.4% 50.9% 3.6 Products/ substances used or intended to be used mainly as cosmetics or toiletries 3.5 Products/ substances used or intended to be used mainly in the household 0.1% Products/ substances 3.4 Products/ substances used or intended to be used used or intended to be used mainly in agriculture mainly in industry 9.5% 9.4%

Figure 3.1
Animals used in toxicological and other safety experiments

In table 3.1 the number of animals used for toxicological or other safety evaluation is broken down into type of products for which testing was required.

Only 8% of the total number of animals used for experimental purposes is used for toxicological and other safety evaluation. This accounts for 1,026,286 animals (see III.3.3)

The percentage of animals used for toxicological evaluation of 4 groups of products/substances, i.e., animal feed, additives for human food consumption, cosmetics and household, is very small (4,3%) when compared to the other products groups.

Products or devices used for human medicine, veterinary medicine and dentistry represents 50,9% of the animal used for toxicological or other safety evaluations.

The group of products/substances falling under the scrutiny of authorities concerned with safety of health and of the environment by chemical products, such as industrial chemicals and pesticides, used 19% of the animals for toxicological and other safety evaluations.

There is a strong decrease in the number of animals used for toxicological tests for products intended for industry, for agriculture, products for potential contaminants of the environment (decrease ranging from above 123,000 to below 98,000) and also tests for products for household and for additives in food for human consumption, categories using lower numbers, in comparison to the data submitted in the last statistical report.

There is a noticeable increase (50%) in the number of animals used for testing cosmetics or toiletries, however, the actual numbers of animals in this category remain low (5,571 in total). This increase, attributed mainly to one old Member State, is worth noting in light of the legal requirement to phase out animal testing for cosmetics in the EU. There is also a significant increase in the number of animals used for tests for additives in food for animal consumption (3,447 to 34,225 - 10 fold).

It should also be noted that in comparison to the 2002 report there is a significant increase in the number of animals used for other toxicological or safety evaluation (ranging from around 110,000 to 180,000). This category could benefit from further analysis. Member States reported that it concerned new methods and tests, such as: tests on transmission of microcystins on embryonic membrane; bioassays; toxicity evaluation for humans via the environment; and control of safety for toys.

Table 3.1: Number of animals used in toxicological and other safety evaluation Products versus species

Data of 2005*

	3.1.Species	3.2. Products/ substances or devices for human medicine and dentistry and for veterinary medicine	3.3. Products/ substances used or intended to be used mainly in agriculture	3.4.Products/ substances used or intended to be used mainly in industry	3.5.Products/ substances used or intended to be used mainly in the household	3.6.Products/ substances used or intended to be used mainly as cosmetics or toiletries	3.7.Products/ substances used or intended to be used mainly as additives in food for human consumption	3.8.Products/ substances used or intended to be used mainly as additives in food for animal consumption	3.9.Potentialor actual contaminants in the general environment which do not appear in other columns	3.10.Othertoxicological or safety evaluations	3.11.Total
1.a.	Mice (Mus musculus)	210 840	18 546	26 677	72	1 797	1 268	1 630	9 264	116 850	386 944
1.b.	Rats (Rattus norvegicus)	210 719	41 903	44 768	294	2 226	2 644	704	8 883	36 707	348 648
1.c.	Guinea-Pigs (Cavia porcellus)	35 123	3 051	7 128	177	940	46	0	156	6 877	53 498
1.d.	Hamsters (Mesocricetus)	1 065	571	18	0	0	0	0	0	16	1 670
1.e.	Other Rodents (other Rodentia)	300	68	28	0	0	0	0	442	0	838
1.f.	Rabbits (Oryctolagus cuniculus)	26 030	3 593	4 433	116	608	141	113	25	4 094	39 153
1.g.	Cats (Felis catus)	222	0	0	0	0	0	0	0	0	222
1.h.	Dogs (Canis familiaris)	12 671	509	278	0	0	0	0	29	1 118	14 605
1.i.	Ferrets (Mustela putorius furo)	41	0	0	0	0	0	0	0	0	41
1.j.	Other Carnivores (other Carnivore)	0	0	0	0	0	0	0	0	0	0
1.k. (Equ		35	5	0	0	0	0	0	0	0	40
1.l.	Pigs (Sus)	2 246	90	47	0	0	76	444	103	241	3 247
1.m.	Goats (Capra)	24	5	0	0	0	0	0	10	0	39
1.n.	Sheep (Ovis)	351	10	0	0	0	0	10	72	14	457
1.0.	Cattle (Bos)	489	48	0	0	0	0	105	0	15	657
1.p.	Prosimians (Prosimia)	97	0	0	0	0	0	0	0	0	97
1.q.	New World Monkeys (Ceboidea)	613	0	0	0	0	0	0	0	37	650
1.r.	Old World Monkeys (Cercopithecoidea)	5 057	0	6	0	0	0	0	0	1 194	6 257
1.s.	Apes (Hominoidea)	0	0	0	0	0	0	0	0	0	0
1.t.	Other Mammals (other Mammalia)	15	0	0	0	0	0	0	0	0	15
1.u.	Quail (Coturnix coturnix)	0	3 161	0	0	0	0	0	25	0	3 186
1.v.	Other birds (other Aves)	9 246	3 728	98	0	0	0	31 119	1 437	5 116	50 744
1.w.	Reptiles (Reptilia)	0	0	0	0	0	0	0	0	12	12
1.x.	Amphibians (Amphibia)	0	400	0	0	0	0	100	0	42	542
1.y.	Fish (Pisces)	6 937	21 944	12 998	560	0	0	0	64 286	7 799	114 524
1.z.	TOTAL	522 121	97 632	96 479	1 219	5 571	4 175	34 225	84 732	180 132	1 026 286

^(*) France reporting for 2004

III.5. Results of EU Table 4: Animals used for studies of diseases

III.5.1. The data on animals used for studies of diseases

The consolidated table of results on animals used for studies of diseases (EU Table 4) in the 25 Member States is presented in Table 4.1 at the end of this chapter.

III.5.2. Treatment and interpretation of the data

Table 4.1 gives the number of animals used per type of studies on diseases. In 2005, the number of animals used for the study of both animal and human diseases represented more than half (57,5%) the total number of animals used for experimental purposes in the EU.

Figure 4.1 presents the percentage of animals used in studies per type of diseases.

The percentage of the number of animals used for studies of human diseases represents 81% of the total number of animals used for all studies of diseases.

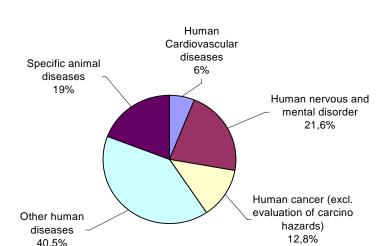


Figure 4.1 Proportion of animals used for the study of diseases

In 2005, the proportion and the number of animals used (ranging from 900,000 to 1,329,000) for the studies of animal diseases have increased significantly when compared with the report of 2002.

It should be remembered that the studies on specific animal diseases are important in the light of epidemics of farm animals such as in the case of cows, foot and mouth disease, swine fever and more recently avian flew. Animals used also covers studies on genetic diseases.

An important part, around 60%, of the increase of the total use of mice (579,000) in comparison with 2002, can be attributed to different studies of diseases.

Table 4.1: Number of animals used in experiments for studies on human and animal diseases

Main category of diseases versus species

Data of 2005 *

4.1 Species	4.2 Human cardiovascular diseases	4.3 Human nervous and mental disorders	4.4 Human cancer (excluding evaluations of carcinogenic hazards or risks)	4.5 Other human diseases	4.6 Studies specific to animal diseases	4.7 Total
1.a. Mice (Mus musculus)	233054	843362	801787	1862317	158718	3899238
1.b. Rats (Rattus norvegicus)	154838	610191	80825	642300	5251	1493405
1.c. Guinea-Pigs (Cavia porcellus)	4721	7581	781	57019	5200	75302
1.d. Hamsters (Mesocricetus)	2121	4471	579	7302	2931	17404
1.e. Other Rodents (other Rodentia)	84	24311	487	12750	3038	40670
1.f. Rabbits (Oryctolagus cuniculus)	11601	3769	631	23941	7864	47806
1.g. Cats (Felis catus)	13	203	52	339	992	1599
1.h. Dogs (Canis familiaris)	1538	367	347	6001	2395	10648
1.i. Ferrets (Mustela putorius furo)	228	159	33	1693	71	2184
1.j. Other Carnivores (other Carnivore)	2	0	0	500	540	1042
1.k. Horses, donkeys and cross breds (Equidae)	8	29	8	110	919	1074
1.I. Pigs (Sus)	4902	943	198	8548	11226	25817
1.m. Goats (Capra)	184	25	3	481	205	898
1.n. Sheep (Ovis)	759	523	52	7138	7953	16425
1.o. Cattle (Bos)	140	1841	0	2608	7727	12316
1.p. Prosimians (Prosimia)	0	383	0	0	0	383
1.q. New World Monkeys (Ceboidea)	58	204	2	810	0	1074
1.r. Old World Monkeys (Cercopithecoidea)	53	167	179	2882	9	3290
1.s. Apes (Hominoidea)	0	0	0	0	0	0
1.t. Other Mammals (other Mammalia)	250	189	3	1777	65	2284
1.u. Quail (Coturnix coturnix)	0	197	0	25	0	222
1.v. Other birds (other Aves)	1443	6282	0	27269	159253	194247
1.w. Reptiles (Reptilia)	13	115	0	24	79	231
1.x. Amphibians (Amphibia)	1067	1338	2923	10297	277	15902
1.y. Fish (Pisces)	300	3898	421	146936	954534	1106089
1.z. TOTAL	417377	1510548	889311	2823067	1329247	6969550

^(*) France reporting for 2004

Table 4.2: Number of animals used in studies of diseases by classes of animals

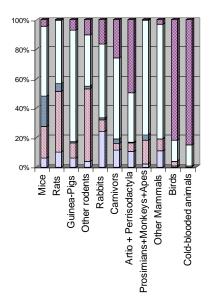
Classes of animals	Human Cardiovascular diseases	Human nervous and mental disorder	Human cancer (excl. evaluation of carcino hazards)	Other human diseases	Specific animal diseases	Total
Mice	233054	843362	801787	1862317	158718	3899238
Rats	154838	610191	80825	642300	5251	1493405
Guinea-Pigs	4721	7581	781	57019	5200	75302
Other rodents	2205	28782	1066	20052	5969	58074
Rabbits	11601	3769	631	23941	7864	47806
Carnivores	1781	729	432	8533	3998	15473
Artio + Perrisodactyla	5993	3361	261	18885	28030	56530
Prosimians+Monkeys+Apes	111	754	181	3692	9	4747
Other Mammals	250	189	3	1777	65	2284
Birds	1443	6479	0	27294	159253	194469
Cold-blooded animals	1380	5351	3344	157257	954890	1122222
TOTAL	417377	1510548	889311	2823067	1329247	6969550

Classes of animals%	Human Cardiovascular diseases	Human nervous and mental disorder	Human cancer (excl. evaluation of carcino hazards)	Other human diseases	Specific animal diseases	Total
Mice	5,98	21,63	20,56	47,76	4,07	100,00
Rats	10,37	40,86	5,41	43,01	0,35	100,00
Guinea-Pigs	6,27	10,07	1,04	75,72	6,91	100,00
Other rodents	3,80	49,56	1,84	34,53	10,28	100,00
Rabbits	24,27	7,88	1,32	50,08	16,45	100,00
Carnivores	11,51	4,71	2,79	55,15	25,84	100,00
Artio + Perrisodactyla	10,60	5,95	0,46	33,41	49,58	100,00
Prosimians+Monkeys+Apes	2,34	15,88	3,81	77,78	0,19	100,00
Other Mammals	10,95	8,27	0,13	77,80	2,85	100,00
Birds	0,74	3,33	0,00	14,04	81,89	100,00
Cold-blooded animals	0,12	0,48	0,30	14,01	85,09	100,00
TOTAL	5,99	21,67	12,76	40,51	19,07	100,00

Species of Table 4.1 were grouped into classes of animals to present Table 4.2. The relative percentage of animals per classes of species used in studies by type of diseases has been calculated and is also presented in the lower part of Table 4.2.

Figure 4.2 presents the proportion of animals used by classes per type of studies of diseases.

Figure 4.2
Proportion of animals used by classes per type of studies of diseases



■ Specific animals diseases %

□ Other human diseases %

■ Human cancer (excl. evaluation of carcino hazards) %

■ Human nervous and mental disorder %

□ Human Cardiovascular diseases%

The top of each bar shows the relative percentage of animals used for studies on specific animal diseases. Two groups of animals i.e. birds and cold-blooded animals account for more than 80% of such studies. Member States reported that it is still current practice to test vaccines on these types of species. However, in some Member States only birds are used if the infection concerns bird species.

In 2005, the proportion of other mammals used for specific animal diseases has decreased but increased proportionally in studies of other human diseases.

Overall the general pattern of the proportion of animals used for the studies of diseases presented very little change when compared to the previous statistical report.

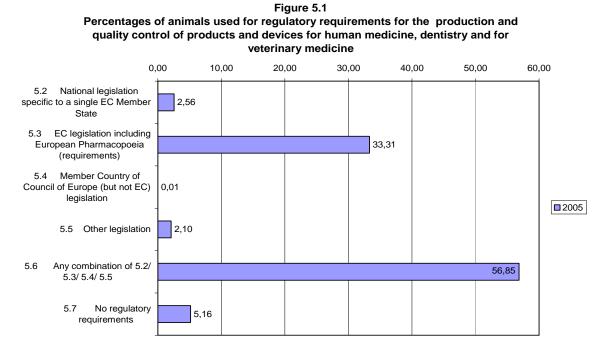
III.6. Results of EU Table 5: <u>Animals used in production and quality control of products for human medicine and dentistry and for veterinary medicine</u>

III.6.1. The data on animals used in production and quality control of products for human medicine and dentistry and for veterinary medicine

The consolidated table for the 25 Member States reporting the origin of the regulatory requirements in relation to animals used for the production and quality control of products for human medicine and dentistry and for veterinary medicine (EU Table 5) is presented in Table 5.1 of this report.

III.6.2. Treatment and interpretation of the data

The number of animals used in tests for the production and quality control of products for human medicine and dentistry and for veterinary medicine represents 15,3% of the total number of animals used for experimental purposes. Figure 5.1 gives the percentages of the animals used for different regulatory purposes in this area.



The largest proportion of animals in this area (57%) was used to simultaneously satisfy requirements from several legislations such as national, Community, Council of Europe or others. The testing carried out to satisfy the EU legislation including the European Pharmacopoeia covered 33,3% of the animals used in this area.

The increase of the percentage, from 43,1% to 56,8%, of the number of animals used to satisfy simultaneously several pieces of legislation in comparison to 2002, is clearly showing an encouraging trend. This is likely to reflect a positive increase in harmonisation of different legislative requirements.

Another positive trend is the reduction of the number of animals, from 352,000 to 95,739, used for "no regulatory requirements".

Table 5.1: Number of animals used in the production and quality control of products and devices for human medicine and dentistry and for veterinary medicine

Regulatory requirements versus species
Data of 2005 *

Data 01 2003										
5.1. Species	5.2. National	5.3. EC legislation	5.4. Member	5.5. Other	5.6. Any	5.7. No	5.8. Total			
	legislation	including	Country of Council	legislation	combination of	regulatory				
	specific to a	European	of Europe (but not		5.2/ 5.3/ 5.4/	requirements				
	single EC	Pharmacopoeia	EC) legislation2)		5.5					
	Member State1	(requirements)								
1.a. Mice (Mus musculus)	24912	326864	20	13463	685435	36912	1087606			
1.b. Rats (Rattus norvegicus)	5551	82479	0	18436	127504	6822	240792			
1.c. Guinea-Pigs (Cavia porcellus)	8558	44713	7	6041	73163	3346	135828			
1.d. Hamsters (Mesocricetus)	0	4528	0	0	5449	395	10372			
1.e. Other Rodents (other Rodentia)	0	0	0	0	187	0	187			
1.f. Rabbits (Oryctolagus cuniculus)	2566	85556	0	308	87867	28300	204597			
1.g. Cats (Felis catus)	76	607	0	13	111	18	825			
1.h. Dogs (Canis familiaris)	21	1016	0	0	241	148	1426			
1.i. Ferrets (Mustela putorius furo)	14	30	0	0	6	6	56			
1.j. Other Carnivores (other Carnivore)	0	202	0	0	0	0	202			
1.k. Horses, donkeys and cross breds (Equidae)	229	219	0	2	281	1429	2160			
1.l. Pigs (Sus)	136	4363	0	9	1572	1019	7099			
1.m. Goats (Capra)	0	4	0	0	118	3	125			
1.n. Sheep (Ovis)	176	838	0	0	3650	2284	6948			
1.o. Cattle (Bos)	125	1462	26	10	533	268	2424			
1.p. Prosimians (Prosimia)	0	0	0	0	0	0	0			
1.q. New World Monkeys (Ceboidea)	0	35	0	0	0	8	43			
1.r. Old World Monkeys (Cercopithecoidea)	0	6	0	0	357	10	373			
1.s. Apes (Hominoidea)	0	0	0	0	0	0	0			
1.t. Other Mammals (other Mammalia)	10	60	0	0	0	0	70			
1.u. Quail (Coturnix coturnix)	0	0	0	0	0	0	0			
1.v. Other birds (other Aves)	3913	61303	152	683	63959	14181	144191			
1.w. Reptiles (Reptilia)	0	0	0	0	0	0	0			
1.x. Amphibians (Amphibia)	0	0	0	0	0	0	0			
1.y. Fish (Pisces)	1222	3446	0	0	3971	590	9229			
1.z. TOTAL	47509	617731	205	38965	1054404	95739	1854553			
(*) France reporting for 2004			·							

(*) France reporting for 2004

Examples: 5.2 - France is testing due to a UK (or FR) specific requirement

5.3 - UK is testing according to EC legislation

5.4 - Spain is testing due to a Hungarian requirement

5.5 - Sweden is testing due to a US specific requirement

5.6 - Germany is testing due to a Czech requirement (also an EC requirement)

columns 5.2 - 5.5 refer to the legislation imposing that the test be carried out

and not to the body which has issued the actual test method, guideline or protocol

a test required by French legislation and carried out in Belgium according to an

ISO protocol must be coded as a national (FR) legislative requirement and be

entered into column 5.2 in the tables submitted by Belgium.

Note:

Example:

III.7. Results of EU harmonized Table 6: <u>Origin of regulatory requirements for animals used in toxicological and other safety evaluations</u>

III.7.1. The data on the origin of regulatory requirements for animals used in toxicological and other safety evaluations

The consolidated table for the 25 Member States reporting data on animals used in toxicological and other safety evaluations in relation to the origin of regulatory requirements (EU Table 6) is presented in Table 6.1 at the end of this chapter.

III.7.2. Treatment and interpretation of the data

It can be observed that the use of animals for regulatory requirements in the area of toxicological or other safety evaluation presented in Figure 6.1 follows a similar pattern to that of the use for regulatory purposes in human medicine, dentistry and in veterinary medicine presented in the Figure 5.1 in the previous chapter.

As pointed out earlier, the number of animals used in toxicological or other safety evaluation represents 8% of the total number of animals used for experimental purposes in the EU.

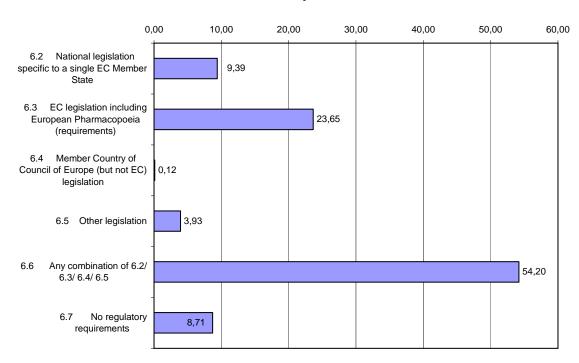


Figure 6.1

Percentages of animals used for regulatory requirements for toxicological and other safety evaluation

Animals used to simultaneously satisfy regulatory requirements from several pieces of legislation covered more than half of the animals used in this area (54,2%). The testing required under the EU legislation including the European Pharmacopoeia accounts for the second highest percentage in this area namely 23%.

It should be underlined that the proportional decrease of the numbers of animals used for toxicological and other safety evaluation since the last report, from 10% to 8%, represents at the same time a decrease of about 40,000 animals. The number of animals used "no regulatory requirements" decreased since the last report from 114,000 to 90,000 animals, a drop of 24,000 animals.

Member States who were asked to provide some further explanation as to the reasons for this clear decrease of animals used for no regulatory requirements compared to previous reports, indicated that the decrease was partially attributed to use of alternative in vitro methods and invertebrate animals. For example, safety pharmacological tests such as those used for supplementary batch control by the European Pharmacopoeia. In order to understand what is meant by the term 'no regulatory requirements', for example some Member States indicated that legal obligations to ensure quality and safety of imported drugs would be reported under this category.

The testing to satisfy national legislation specific to a single Member State showed a decrease in this report with respect to the previous one but it represents about 15,500 animals i.e. 1,5% of the total number used for toxicological and other safety evaluation.

Table 6.1: Number of animals used in toxicological and other safety evaluations

Regulatory requirements versus species

Data of 2005*

6.1. Species	6.2. National legislation specific to a single EC Member State1)	6.3. EC legislation including European Pharmacopoeia (requirements)	6.4. Member Country of Council of Europe (but not EC) legislation2)	6.5. Other legislation	6.6. Any combination of 5.2/ 5.3/ 5.4/ 5.5	6.7. No regulatory requirements	6.8.Total
1.a. Mice (Mus musculus)	39972	104143	170	15039	189776	37144	386244
1.b. Rats (Rattus norvegicus)	19368	61953	670	15875	224860	25772	348498
1.c. Guinea-Pigs (Cavia porcellus)	1009	21189	70	2052	27849	1329	53498
1.d. Hamsters (Mesocricetus)	0	182	0	0	1204	284	1670
1.e. Other Rodents (other Rodentia)	0	300	0	0	0	583	883
1.f. Rabbits (Oryctolagus cuniculus)	1398	9462	13	2653	23162	2420	39108
1.g. Cats (Felis catus)	166	46	0	6	4	23	245
1.h. Dogs (Canis familiaris)	977	1919	0	520	10842	324	14582
 Ferrets (Mustela putorius furo) 	0	0	0	0	41	0	41
1.j. Other Carnivores (other Carnivore)	0	0	0	0	0	0	0
Horses, donkeys and cross breds (Equidae)	0	5	0	0	25	10	40
1.l. Pigs (Sus)	57	1150	0	132	1642	266	3247
1.m. Goats (Capra)	0	26	0	0	3	44	73
1.n. Sheep (Ovis)	4	120	0	0	191	108	423
1.o. Cattle (Bos)	12	320	0	15	203	107	657
1.p. Prosimians (Prosimia)	0	97	0	0	0	0	97
1.q. New World Monkeys (Ceboidea)	0	0	0	0	599	51	638
1.r. Old World Monkeys (Cercopithecoidea)	0	304	0	488	5312	153	6257
1.s. Apes (Hominoidea)	0	0	0	0	0	0	0
1.t. Other Mammals (other Mammalia)	0	15	0	0	0	0	15
1.u. Quail (Coturnix coturnix)	0	2124	0	0	1037	25	3186
1.v. Other birds (other Aves)	5519	4787	0	522	38262	1654	50744
1.w. Reptiles (Reptilia)	12	0	0	0	0	0	12
1.x. Amphibians (Amphibia)	542	0	0	0	0	0	542
1.y. Fish (Pisces)	27338	34565	312	3029	31210	19120	115574
1.z. TOTAL	96374	242707	1235	40331	556222	89417	1026286

(*)France reporting for 2004

Examples: 6.2 - France is testing due to a UK (or FR) specific requirement

6.3 - UK is testing according to EC legislation

6.4 - Spain is testing due to a Hungarian requirement

6.5 - Sweden is testing due to a US specific requirement

6.6 - Germany is testing due to a Czech requirement (also an EC requirement)

Note: columns 6.2 - 6.5 refer to the legislation imposing that the test be carried out and not to

the body which has issued the actual test method, guideline or protocol

a test required by French legislation and carried out in Belgium according to an

ISO protocol must be coded as a national (FR) legislative requirement and be

entered into column 6.2 in the tables submitted by Belgium.

III.8. Results of EU Table 7: <u>Animals used in toxicity test for toxicological and other safety</u> evaluations

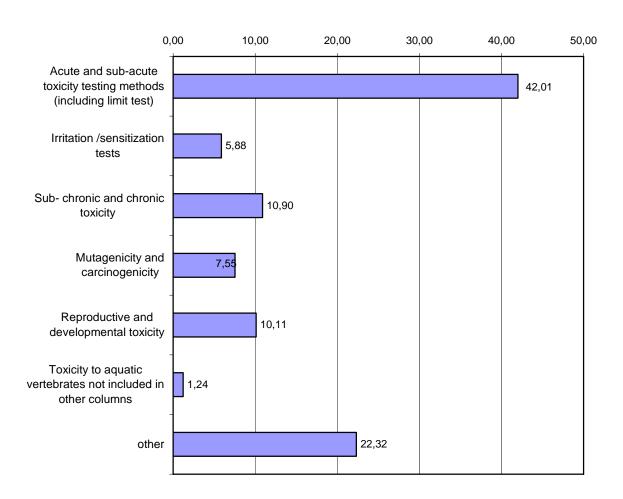
III.8.1. The data on animals used in toxicity test for toxicological and other safety evaluations

The consolidated table for the 25 Member States reporting on animals used in toxicity tests for the purpose of toxicological and other safety evaluations of products (EU Table 7) is presented in Table 7.1 at the end of this chapter.

III.8.2. Treatment and interpretation of the data

For the convenience of the presentation of results some of the toxicity tests of Table 7.1 have been grouped according to systemic and local toxicity and CMR effects in Table 7.2 of this report. A graph showing the percentage of animals used per toxicity test groups in 2005 is presented in Figure 7.1

Figure 7.1
Percentages of animals used in toxicity tests for toxicological and other safety evaluation



As pointed out in the previous chapter, the number of animals used in toxicological and other safety evaluation represents 8% of the total number of animals used for experimental purposes.

It can be seen in Figure 7.1 that the largest percentage of use of animals is due to acute and sub-acute toxicity tests 42% in 2005. Taking also into account sub-chronic and chronic toxicity, the percentage of animals used in short and long term systemic toxicity testing accounts for 53% of the experimental animals used in this area.

About 17,5% of animals were used for testing carcinogenicity, mutagenicity and toxicity to reproduction in 2005. Another important category of use of animals in 2005 is for "other tests" with 22,3%. Breaking down further the category 'other', Member States reported testing in areas such as biological screening for pharmaceutical, healthcare and veterinary products. This includes neurotoxicity, toxicokinetics, testing of acute dermal toxicity, testing of biological evaluation of medical devices: Intracutan testing of reactivity on rabbits, study into penetration of nanoparticle through tissue and their biocompatibility, study into evaluation of sensitization potential of dyestuffs used in textile industry and pharmacological studies included in safety tests.

By looking both in numbers and relative percentages of use of animals in comparison to the previous reports there are three noticeable changes:

One can observe a continuous increase over the last three reports of the proportion of animals used for acute and sub-acute tests ranging from: 32%, 36% to 42% respectively. This represents in animal numbers an increase of 39,000 animals since the last report of 2002. Member States attributed the increase in part to several phases in new product development and new legislation for example requiring that all generic substances should be tested.

On the other hand one can observe a steady decrease over the last three reports of the proportion of animals used for toxicity tests to reproduction going down from: 15%, 12% to 10% respectively.

Another important decrease in the proportion of animals used is the decrease from 4,5% to 1,2% of animals used in toxicity test to aquatic vertebrates.

Some Member States presume that the decrease in regulatory testing can indeed be attributed to alternative methods but others think that replacement methods have a much greater impact on R&D than on regulatory requirements. They point out that the statistics drawn up annually include re-use of animals which plays an important role.

Table 7.1: Number of animals used in toxicological and other safety evaluations

Type of tests versus species Data of 2005*

7.1. Species		and sub-act nods (includii		7.3. Skin irritation	7.4. Skin sensitis ation	7.5. Eye irritation	7.6. Sub- chronic and chronic toxicity	7.7. Carcino- genicity	7.8. Develop- mental toxicity	7.9. Muta- genicity	7.10. Reproductive toxicity	7.11. Toxicity to aquatic vertebra-tes not included in other columns	7.12. Other	7.13. Total
	7.2.1. LD50, LC50	7.2.2. Other lethal methods	7.2.3. Non lethal clinical signs methods											
1.a. Mice (Mus musculus)	33024	86669	68682	2805	21350	0	25550	19624	2612	19479	908	0	105541	386244
1.b. Rats (Rattus norvegicus)	19756	18614	78707	1156	303	142	65466	22400	23886	15727	51518	0	50829	348504
1.c. Guinea-Pigs (Cavia porcellus)	1415	993	17572	2144	22184	0	628	0	0	0	0	0	8556	53492
1.d. Hamsters (Mesocricetus)	0	64	603	0	0	0	38	0	0	20	0	0	945	1670
1.e. Other Rodents (other Rodentia)	56	142	300	0	0	0	300	0	0	0	0	0	40	838
1.f. Rabbits (Oryctolagus cuniculus)	36	49	2944	5130	52	4033	1693	0	8078	31	4640	0	12467	39153
1.g. Cats (Felis catus)	0	0	108	0	0	0	0	0	0	0	0	0	114	222
1.h. Dogs (Canis familiaris)	182	659	5170	0	0	0	6998	0	0	0	29	0	1567	14605
1.i. Ferrets (Mustela putorius furo)	0	0	41	0	0	0	0	0	0	0	0	0	0	41
1.j. Other Carnivores (other Carnivore)	0	0	0	0	0	0	0	0	0	0	0	0	0	0
 Horses, donkeys and cross breds 	0	0	10	0	0	0	0	0	0	0	0	0	30	40
(Equidae)						_		_						
1.l. Pigs (Sus)	8	49	304	8	0	0	971	0	89	0	100	0	1718	3247
1.m. Goats (Capra)	0	0	0	0	0	0	0	0	0	0	0	0	39	39
1.n. Sheep (Ovis)	0	0	32	0	0	0	0	0	35	0	37	0	353	457
1.o. Cattle (Bos)	0	0	73	0	0	0	0	0	0	0	0	0	584	657
1.p. Prosimians (Prosimia)	0	0	60	0	0	0	32	0	0	0	0	0	5	97
1.q. New World Monkeys (Ceboidea)	0	85	222	0	0	0	185	0	90	0	0	0	68	638
1.r. Old World Monkeys (Cercopithecoidea)	0	1	2014	0	0	33	3406	0	131	0	187	0	485	6257
1.s. Apes (Hominoidea)	0	0	0	0	0	0	0	0	0	0	0	0	0	0
1.t. Other Mammals (other Mammalia)	0	0	0	0	0	0	0	0	0	0	0	0	15	15
1.u. Quail (Coturnix coturnix)	2253	348	105	0	0	0	0	0	0	0	480	0	0	3186
1.v. Other birds (other Aves)	1671	260	11403	1000	0	0	158	0	0	0	128	0	36124	50744
1.w. Reptiles (Reptilia) 1.x. Amphibians (Amphibia)	0	0	0	0	0	0	0	0	0	0	0	0	12	12
1 ,	0	0	0	0	0	0	0	0	42	0	0	0	500	542
1.y. Fish (Pisces)	54830	10449	11146	0	0	0	6443	0	5484	226	5284	12675	9037	115574
1.z. TOTAL	113231	118382	199496	12243	43889	4208	111868	42024	40447	35483	63311	12675	229029	1026286

^(*) France reporting for 2004

Table 7.2: Grouping of certain type of tests on animals of table 7.1

7.1. Species	Acute and sub-acute toxicity testing methods (including limit test)	Irritation /sensitization tests	Sub- chronic and chronic toxicity	Mutagenicity and carcinogenicity	Reproductive and developmental toxicity	Toxicity to aquatic vertebrates not included in other columns	other	Total
1.a. Mice (Mus musculus)	188375	24155	25550	39103	3520	0	105541	386244
1.b. Rats (Rattus norvegicus)	117077	1601	65466	38127	75404	0	50829	348504
1.c. Guinea-Pigs (Cavia porcellus)	19980	24328	628	0	0	0	8556	53492
1.d. Hamsters (Mesocricetus)	667	0	38	20	0	0	945	1670
1.e. Other Rodents (other Rodentia)	498	0	300	0	0	0	40	838
1.f. Rabbits (Oryctolagus cuniculus)	3029	9215	1693	31	12718	0	12467	39153
1.g. Cats (Felis catus)	108	0	0	0	0	0	114	222
1.h. Dogs (Canis familiaris)	6011	0	6998	0	29	0	1567	14605
1.i. Ferrets (Mustela putorius furo)	41	0	0	0	0	0	0	41
1.j. Other Carnivores (other Carnivore)	0	0	0	0	0	0	0	0
1.k. Horses, donkeys and cross breds (Equidae)	10	0	0	0	0	0	30	40
1.l. Pigs (Sus)	361	8	971	0	189	0	1718	3247
1.m. Goats (Capra)	0	0	0	0	0	0	39	39
1.n. Sheep (Ovis)	32	0	0	0	72	0	353	457
1.o. Cattle (Bos)	73	0	0	0	0	0	584	657
1.p. Prosimians (Prosimia)	60	0	32	0	0	0	5	97
1.q. New World Monkeys (Ceboidea)	307	0	185	0	90	0	68	638
1.r. Old World Monkeys (Cercopithecoidea)	2015	33	3406	0	318	0	485	6257
1.s. Apes (Hominoidea)	0	0	0	0	0	0	0	0
1.t. Other Mammals (other Mammalia)	0	0	0	0	0	0	15	15
1.u. Quail (Coturnix coturnix)	2706	0	0	0	480	0	0	3186
1.v. Other birds (other Aves)	13334	1000	158	0	128	0	36124	50744
1.w. Reptiles (Reptilia)	0	0	0	0	0	0	12	12
1.x. Amphibians (Amphibia)	0	0	0	0	42	0	500	542
1.y. Fish (Pisces)	76425	0	6443	226	10768	12675	9037	115574
1.z. TOTAL	431109	60340	111868	77507	103758	12675	229029	1026286

III.9. Results of EU Table 8: <u>Type of toxicity tests carried out for toxicological</u> and other safety evaluations of products

III.9.1. The data on type of toxicity tests carried out for toxicological and other safety evaluations of products

The consolidated table for the type of toxicity tests carried out for toxicological or other safety evaluations of products, for the 25 Member States reporting (EU Table 8) is presented in Table 8.1 of this report. There are discrepancies between the total numbers of animals *per types of tests* in Table 7 in comparison with the total numbers of animals *per types of tests* of Table 8. Logically these should be the same. These discrepancies originate from 10 Member States; however, when the data was submitted no explanation was given as to the reasons. The overall total number of animals for toxicological and other safety evaluations remains coherent.

III.9.2. Treatment and interpretation of the data

As pointed out earlier it is important to keep in mind that animals used in toxicological and other safety evaluation represent 8% of the total number of animals used for experimental purposes. The treatment and interpretation of the data on animals used for toxicity tests with regard to the type of products has not been done in the previous reports due to inconsistencies in the data in the past. The results in this area are therefore analysed and compared in this report for the first time.

Figure 8.1 represents the percentages of the number of animals used in toxicological testing or other safety evaluations in relation to the type of products or purposes. In order to give a better graphical presentation of the results, some type tests have been grouped according to systemic and local toxicity and carcinogenic, mutagenic and toxicity to reproduction effects in Table 8.2 of this report.

Figure 8
Percentages of animals used for toxicity tests for toxicological and other safety evaluation by types of products

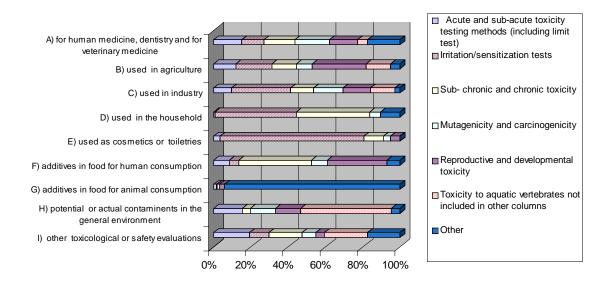


Figure 8.1 shows a decrease in the proportion of animals used in acute and sub-acute toxicity tests in comparison with other tests when moving down in the graph for products used A) for human medicine, dentistry and veterinary medicine, B) for agriculture, C) for industry, D) for household, E) for cosmetics, F) for additives in food consumption and G) for additives in food for animal consumption. However, the animals used in acute and sub-acute toxicity tests for other toxicological and safety evaluations would benefit from further analysis.

Contrary to acute and sub-acute toxicity one can observe an increase in the proportion of animals used for irritation and sensitization tests. While further down the graph amongst the four first types of products, a maximum amount of testing takes place for products used in cosmetics and toiletries.

The proportion of animals used in sub-chronic and chronic testing seems to follow the same pattern as for irritation sensitization tests with the highest proportion used for D) household products and F) additives in food for human consumption.

The pattern of use of carcinogenicity, mutagenicity and toxicity to reproduction tests is rather scattered between the different types of products and more difficult to interpret.

The proportion of animals used for G) additives in food for animal consumption is governed by about 90% by other tests. This group would benefit from further analysis.

Table 8.1: Number of animals used in toxicological and other safety evaluations

Type of tests versus products

Data of 2005*

8.1. Products		and sub-acu nods (includir		8.3. Skin irritation	8.4. Skin sensitisat ion	8.5. Eye irritatio n	8.6. Sub- chronic and chronic toxicity	8.7. Carcino- genicity	8.8. Develop - mental toxicity	8.9. Muta- genicity	8.10. Repro- ductive toxicity	8.11. Toxicity to aquatic vertebra-tes not included in other columns	8.12. Other	8.13. Total
	8.2.1. LD50, LC50	8.2.2. Other lethal methods	8.2.3. Non lethal clinical signs methods											
8.a. Products/ substances or devices for human medicine and dentistry and for veterinary medicine	18820	38091	155459	4097	15296	1452	67651	26589	18238	21005	30788	3419	127284	528189
8.b. Products/ substances used or intended to be used mainly in agriculture	21368	5956	11467	872	6486	654	12535	3100	10158	1831	12599	1847	8687	97560
8.c. Products/ substances used or intended to be used mainly in industry	18963	4047	13416	4743	9264	1111	13177	2644	3230	8371	10043	2136	5684	96829
8.d. Products/ substances used or intended to be used mainly in the household	20	18	11	48	154	70	568	3	0	51	0	0	276	1219
8.e. Products/ substances used or intended to be used mainly as cosmetics or toiletries	0	349	684	469	2222	300	966	0	368	213	0	0	0	5571
8.f. Products/ substances used or intended to be used mainly as additives in food for human consumption	6	40	1283	3	98	3	1767	0	0	239	1210	0	572	5221
8.g. Products/ substances used or intended to be used mainly as additives in food for animal consumption	0	907	239	30	0	0	160	24	0	0	423	0	31692	33475
8.h. Potential or actual contaminants in the general environment which do not appear in other columns	32120	9894	5959	0	0	0	3793	7045	4541	594	5393	6524	7885	83748
8.i. Other toxicological or safety evaluations	20974	58282	8840	668	4921	478	23062	1459	2756	4836	2088	4593	41517	174474
8.j. TOTAL	112271	117584	197358	10930	38441	4068	123679	40864	39291	37140	62544	18519	223597	1026286

^(*) France reporting for 2004

Table 8.2: Number of animals used in toxicological and other safety evaluation per types of products

8.1. Products	Acute and sub-acute toxicity testing methods (including limit test)	Irritation/sensitization tests	Sub- chronic and chronic toxicity	Mutagenicity and carcinogenicity	Reproductive and developmental toxicity	Toxicity to aquatic vertebra-tes not included in other columns	Other	Total
8.a. Products/ substances or devices for human medicine and dentistry and for veterinary medicine	212370	20845	67651	47594	49026	3419	127284	528189
8.b. Products/ substances used or intended to be used mainly in agriculture	38791	8012	12535	4931	22757	1847	8687	97560
8.c. Products/ substances used or intended to be used mainly in industry	36426	15118	13177	11015	13273	2136	5684	96829
8.d. Products/ substances used or intended to be used mainly in the household	49	272	568	54	0	0	276	1219
8.e. Products/ substances used or intended to be used mainly as cosmetics or toiletries	1033	2991	966	213	368	0	0	5571
8.f. Products/ substances used or intended to be used mainly as additives in food for human consumption	1329	104	1767	239	1210	0	572	5221
8.g. Products/ substances used or intended to be used mainly as additives in food for animal consumption	1146	30	160	24	423	0	31692	33475
8.h. Potential or actual contaminants in the general environment which do not appear in other columns	47973	0	3793	7639	9934	6524	7885	83748
8.i. Other toxicological or safety evaluations	88096	6067	23062	6295	4844	4593	41517	174474
8.j. TOTAL	427213	53439	123679	78004	101835	18519	223597	1026286

PART B: DATA AND SUMMARY OF THE COMMENTS SUBMITTED BY THE MEMBER STATES

AUSTRIA

Statistical data submitted

The statistical data have been submitted by the "Bundesministerien für Gesundheit und Frauen- Land und Forstwirtshaft, Umwelt und Wasserwirtschaft – Wirtschaft und Arbeit - Bildung, Wissenschaft und Kultur" (Federal Ministries for Health and Women -Agriculture Forestry, the Environment and Water Mangement – Economic Affairs and Labour - Education, Science and Culture).

Comments from the Austrian authorities

In accordance with Directive 86/609/EEC regarding the protection of animals used for experimental and other scientific purposes, animal experiments in Austria are regulated by the **Tierversuchsgesetz** (Animal Experiments Act) (Federal Law of 27 September 1989 on experiments using live animals, Federal Law Gesetz, (BGBL. No 501/1989, as most recently amended by Federal Law No.162/2005. Responsibility for enforcing the Animal Experiments Act in Austria rests with the Federal Minister for Health and Women, the Federal Minister for Economic affairs and Labour, the Federal Minister for Agriculture, Forestry, the Environment and Water Management and the Federal Minister for Education, Science and Culture.

Animal experiments are permitted in Austria only if the **stringent requirements of the Animal Experiments Act** are met and only for one of the **following reasons**:

- a) for research and development
- b) for vocational training
- c) for medical diagnosis and therapy
- d) for testing natural or synthetic materials, preparations or products
- e) for detecting environmental risks
- f) for obtaining materials

Animal experiments may only be carried out providing that

- 1. There is a justified interest in carrying out the experiment, i.e.
- a) for preventing, detecting or curing diseases in human beings or animals,
- b) for detecting or influencing physiological conditions or functions in human beings or animals,
- c) for securing scientific knowledge
- d) for providing vocational training or,

- e) for obviating environmental risks, and providing that
- 2. The objectives pursued by the experiments cannot be achieved by other methods or procedures (alternative techniques) or, in the case of vocational training, by using other teaching aids, in particular films or other audiovisual media.

Experiments on animals are never permitted,

- a) if the results of a similar experiment are de facto and de jure accessible and no justified doubts exist as to the accuracy and meaningfulness of the said results,
- b) if no further or new knowledge is likely to come from the experiment,
- c) if the experiment is not necessary, even for control purposes, or
- d) if the results of an animal experiment carried out in Austria or abroad are de facto or de jure accessible, no justified doubts exist regarding the accuracy and meaningfulness of those results and they are officially recognised in Austria on the basis of the relevant statutory provisions.

In addition to the above, the competent Federal Ministers can issue regulations determining which methods are no longer permitted for animal experiments since they are outdated in the light of scientific progress achieved. By way of example, the "LD-50" test has been banned in Austria since 1992.

The Animal Experiments Act directly prohibits the following:

- animal experiments for cosmetic purposes (since 1999), and
- animal experiments involving the Great Apes (since 1. 1. 2006).

Guiding principles

The Animal Experiments Act also contains guiding principles for all scientists and other personnel involved in animal experiments and these are binding, also on the competent authorities. Particular features of these are that:

Animal experiments must be consistent with the principles of scientific research and the hypothesis being tested and the procedure selected must be reasonable in the light of acknowledged scientific progress. Animal experiments are to be conducted with a view to obtaining as much new knowledge as possible.

The meaningfulness and practicability of model animal experiments are to be continuously and critically assessed with a view to reducing the number of animal experiments and increasing the use of alternative techniques, adapting them to reflect acknowledged scientific progress. Results obtained from behavioural research and animal experiments as well as developments in measurement and laboratory techniques are to be taken into account in order to minimize the stress that experimental animals undergo.

All persons involved in carrying out animal experiments are responsible in **ethical and scientific terms** for the tasks they are required to undertake. It is the duty of every scientist to assess the necessity and appropriateness of the animal experiment that he has planned, headed and completed, weighing them against the stress to which the animals are subjected.

Accordingly, Austria's Animal Experiments Act has express provision, as a legal requirement, for applying the principles of the '3 Rs' (reduction, refinement, replacement).

As regards the keeping of experimental animals (caring for and housing the animals) Austria's legislation on animal experiments has not only fully transposed the **guidelines** set out in **Annex II** to Article 5 of Directive 86/609/EEC by law and regulation, but in the interests of animal welfare and of considerably **improving the standards of animal husbandry, it has also made these provisions legally binding**.

Promoting alternatives to animal experiments as a legal obligation

The Federal Ministers responsible for enforcing the Animal Experiments Act (see above) are required by law (the Animal Experiments Act) to promote the development of alternative methods and procedures that do not involve animal experiments (see above) in line with the relevant Federal financial legislation and progress in science and to promote alternative methods and procedures. The aim is to develop alternative methods that are scientifically meaningful and which make it possible to reduce the number of experimental animals and the stress to which they are exposed or even to make animal experiments wholly redundant.

Promoting the objective of the 3Rs is thus an express component of Austria's Animal Experiments Act, the aim being to improve the protection of animals. Over the last decade more than EUR 2.5 million has been spent on researching and developing alternatives to animal experiments, in particular on the part of the Federal Ministry for Education, Science and Culture. Austria also supports, wherever possible, the development, validation and use of alternatives to animal experiments at international level, in particular in the context of the EU and the OECD.

It should also be remembered in this connection that conferences on animal experiments and alternative methods have in the past been organised under Austrian Presidency. By way of example, in November 1998 a conference was organised in conjunction with the European Commission on the subject of "Implementation of the 3 Rs – Objectives for the EU and for science and industry". The aim of this symposium was to promote the implementation of the 3Rs also at EU level. The symposium was attended by the competent authorities from all EU Member States as well as, for the first time, representatives of the third countries that have meanwhile become EU Member States. One of the resolutions adopted at this symposium was forwarded to the Council of Ministers of the EU and to the European Commission for further action. At the beginning of **July 2006** the 13th **Congress on Alternatives to Animal Testing** (meanwhile a tradition) was held in Linz under the patronage of the Austrian EU Presidency offering a much-acclaimed scientific programme on alternatives to animal experiments.

During its EU Presidency in the first half of 2006 Austria sought, in addition to the above, to secure a decision of the Council on the position of the European Community with regard to the proposal to amend Annex A of the European Convention on protecting animals used for experiments and other scientific purposes (see Council of the European Union 7643/06 Legislative Acts and other legal instruments, adopted by the Council on 10 April 2006). As a result, it was possible to ensure that at the fourth multilateral hearing of the parties to this European Convention the European Commission, on behalf of the European Community, was able to support and adopt this revised Appendix A of the Convention that contained guidelines for the housing and care of such animals.

Statistics on animal experiments

Statistics on animal experiments in Austria are produced in accordance with Article 13 of Directive 86/609/EEC pursuant to § 16 of the Animal Experiments Act and the Regulation on Statistics relating to Animal Experiments (Tierversuchsstatistik-Verordnung), which is based on it (BGBl. II No 199/2000), and sets out the standardised statistics for animal experiments which are to be produced annually and be of a binding nature. No later than 1 March every year persons responsible for carrying out animal experiments must submit to the ministry responsible for enforcing the Animal Experiments Act their statistical data relating to their animal experiments during the previous year. The following information is to be provided:

- a) the number and type of experimental animals used overall plus the origin and number, with breakdown, of the animals used,
- b) the number and types of animals used (types of experimental animals, with breakdown),
- c) the number and types of experimental animals used for toxicological and other safety tests,
- d) the number and types of experimental animals used for tests on human and animal diseases,
- e) the number and types of experimental animals used in the manufacture and quality control of products and equipment for human medicine, dentistry and veterinary medicine including, where appropriate, an indication of the relevant statutory provisions,
- f) the number and types of animals used for toxicological and other safety tests, where appropriate with an indication of the relevant statutory provisions as well as the type of test (technique) and products or materials (types of products or materials).

The Federal Ministers responsible for enforcing the Animal Experiments Act are required to produce, by 30 June of every year, a summary report on animal experiment statistics relating to the previous year and publish it in Austria's Official Journal (Amtsblatt zur Wiener Zeitung).

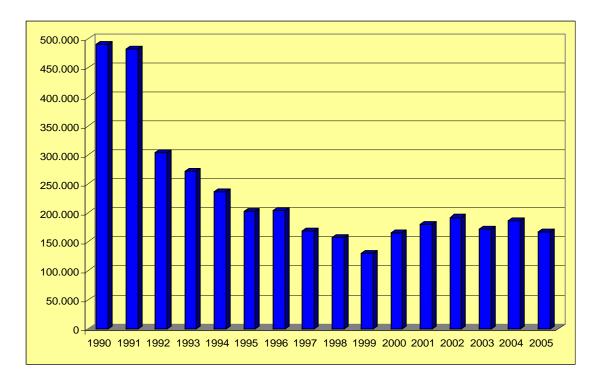
Statistics on animal experiments for 2005

Compared with the previous year there were 10% fewer animal experiments

Compared with other countries there were few animal experiments

As shown in Austria's Official Journal dated 29 June 2006, the 2005 animal experiment statistics show that in 2005 a total of 167,312 animals were used in experiments. This is the lowest figure since 2001.

Compared with earlier years, this indicates a further reduction in the number of animal experiments in Austria as a whole within the "fluctuating" numbers of the past few years (ranging from 160,000 to 200,000). The number of experimental animals is therefore again significantly lower than those for the previous years; for example, in 1996 the number totalled was 203,825, in 1993 it was 272,371 and in 1992 it was 304,308. Compared with 1991 (the first year of statistical coverage) the number of animals used has remained low (at less than 35%). In that year there were 482,166 animals used for experiments, in other words numbers have dropped since then by more than 65%.



The full statistics on animal experiments with all tables produced by the Federal Ministries responsible for enforcing the Animal Experiments Act, namely the Federal Ministry for Health and Women, the Federal Ministry for Economic affairs and Labour, the Federal Ministry for Agriculture, Forestry, the Environment and Water Management and the Federal Ministry for Education, Science and Culture, can be found on the home page of the Federal Ministry for Education, Science and Culture using the following link http://www.bmbwk.gv.at/tierversuche/statistik2005

Animal experiments for human beings and animals

The figures for animal experiments in 2005 – primarily on mice and rats – can be explained in general terms by an increase in biomedical research and a rise in the number of biomedical and bioscientific as well as pharmaceutical firms conducting research, in particular research and development of products for human and veterinary medicine, along with the manufacture and quality control of vaccines that are manufactured for the world market to control major diseases, primarily cancer, leukaemia, diseases of the heart and circulation and AIDS. Cancer research concentrates primarily on the development of improved and more effective therapies that are less stressful for patients.

The figures for animal experiments in the field covered by the Federal Ministry for Health and Women have their origin in an increase in the number of samples taken for the (required) quality control as well as the establishment of new standards for pharmaceutical products undergoing development and new research projects, for example the development and production of human vaccines and therapeutic products. The greater emphasis placed on the development of medical and pharmaceutical medicaments means that despite every effort to find alternative methods, animal experiments are, with a view to protecting the health and safety of human beings **and** animals, indispensable as a preliminary stage prior to any decision on clinical trials on humans.

Lastly, animal experiments are necessary for the animal health as such, i.e. for the development of pharmaceutical products for animals by means of clinical tests on and for animals and this has meant that slightly more dogs and cats have been used. Animal experiments are also necessary for the development of diagnostic and therapeutic measures for animals as well, examples being procedures

for the early detection of cardiac insufficiency in cats or clinical studies on vaccines to control infectious diseases in dogs.

Rats and Mice are the primary experimental animals

In 2005 of the 167 312 animals that were used for experiments in Austria, **140 554** (compared with 158 361 in 2004 and 148.382 in 2003) were rats and mice,

3 140 (2004: 4 158 and 2003: 4 958) were guinea pigs; 18 439 (2004: 20 654 and

2003: 13 928) were rabbits, 1 664 were useful domestic farm animals, (sheep, goats, pigs, and cattle etc.), 1 011 were birds, 992 were fish, 865 were amphibians, 85 were dogs (2004: 155 and 2003: 139) and 12 (2004: 18 and 2003: 22) were cats.

No animal experiments for cosmetics

The statutory ban on the use of animals for experiments for cosmetics that has been in place since 1999 has meant that in accordance with §(5) of the Animal Experiments Act it goes without saying that no animal experiments were conducted in Austria for cosmetics. Austria is in this respect particularly committed to protecting Europe's animals.

No primates for experimental purposes

Statutory ban on experiments on or involving primates.

It can happily be reported that in 2005 Austria continued to forgo the use of primates for animal experiments. This is consistent with the pan-European call for restricting such animal experiments as far as possible and replacing them totally in line with "scientific progress". In 2005 the Federal Ministry for Education Science and Culture resubmitted – on the basis of a Resolution of the National Council of December 2004 and following a general examination – a Parliamentary Bill to the National Council for a statutory ban on animal experiments involving primates, which it adopted in December 2005. The provision entered into force on 1 January 2006.

Austria's figures for animal experiments are comparatively low in international terms

With a total of 167.312 experimental animals (primarily mice and rats) used in 2005, Austria had significantly fewer animal experiments in international terms as well as in terms of the animals used for such experiments. By way of example, neighbouring Switzerland used 550 000 animals for experimental purposes in 2005.

These comparatively low figures for the animals used in animal experiments – accounting for a 65% drop since 1991 – can be explained by at least two inter-related lines of development in relation to animal experiments:

1.) The Three "Rs"

Firstly, 'Reduction, Refinement, Replacement' in relation to animal experiments conducted by scientists, researchers and practical scientists themselves as well as ensuring, as far as possible, the availability of alternative methods to replace animal experiments as this is expressly required by Austria's Animal Experiments Act.

2) Restrictions on the authorization of animal experiments and the promotion of alternative techniques

Secondly, a more restrictive approach on the part of all of the competent authorities to the authorisation of animal experiments in line with the strict requirements of the Animal Experiments Act, which has undergone further improvement since 1999/2000, as have animal experiment regulations in Austria, in accordance with which animal experiments are only permitted subject to very severe restrictions and can be expressly authorised only if the objectives pursued in the experiment cannot be achieved by other methods or procedures (alternative techniques).

Last but not least, it is the public motivation prompted by the award of **national prizes** or **promoting research projects for alternative techniques** as well as propagating at national and international level the use of alternatives to animal experiments that has led to an enhanced awareness of responsibility on the part of the general public with regard to science/research involving animal experiments.

Greater effort to promote the development of alternatives to animal experiments

In September of last year the Federal Ministry for Education, Science and Culture in agreement with all the other Federal Ministries responsible for enforcing the Animal Experiments Act (Federal Ministries for Health and Women, for Economic Affairs and Labour and for Agriculture and Forestry, the Environment and Water) renewed its public call for the submission of research projects targeting alternatives to animal experiments, the aim of which is to provide greater support for alternatives to animal experiments which will be determined ultimately by the number and scale of the projects that are submitted.

It was only last year that the public call for projects by the Federal Ministry for Education Science and Culture was again used to award a **national prize for alternatives to animal experiments**, in other words particular recognition by the State of scientific results already achieved.

TABLE 1: NUMBER OF ANIMALS USED IN RELATION TO THEIR PLACE OF ORIGIN

Origin versus species

1.1	1.2	1.3	1.4	1.5	1.6	1.7
Species	Total	Animals coming from registered	Animals coming from	Animals coming from	Animals coming from	Re-used animals
		breeding or supplying	elsewhere in the EC	Member Countries of the	other origins	
		establishments within the reporting		Council of Europe which are		
		country		parties to the Convention ETS		
				123 (excluding EC Member		
1 16 04	400.004	00.400	00.700	States)	070	50
1.a. Mice (Mus musculus)	128 634	28 469	99 702	184	279	59
1.b. Rats (Rattus norvegicus)	11 920	5 278	6 642	0	0	47
1.c. Guinea-Pigs (Cavia porcellus)	3 149	340	2 809	0	0	0
1.d. Hamsters (Mesocricetus)	117	0	117	0	0	0
1.e. Other Rodents (other <i>Rodentia</i>)	107	60	25	0	22	0
1.f. Rabbits (Oryctolagus cuniculus)	18 439	11 165	7 253	0	21	41
1.g. Cats (Felis catus)	12	0	2	0	10	10
1.h. Dogs (Canis familiaris)	85	67	0	0	18	7
1.i. Ferrets (Mustela putorius furo)	0	0	0	0	0	0
1.j. Other Carnivores (other <i>Carnivore</i>		0	0	0	0	0
 Horses, donkeys and cross breds (1 /	21	0	0	50	12
1.1. Pigs (<i>Sus</i>)	818	594	61	0	163	41
1.m. Goats (Capra)	44	20	0	0	24	3
1.n. Sheep (Ovis)	195	127	20	0	48	34
1.o. Cattle (Bos)	536	352	16	0	168	9
1.p. Prosimians (<i>Prosimia</i>)	0	0	0	0	0	0
1.q. New World Monkeys (Ceboidea)	0	0	0	0	0	0
1.r. Old World Monkeys (Cercopithed	coidea) 56	56	0	0	0	41
1.s. Apes (Hominoidea)	0	0	0	0	0	0
1.t. Other Mammals (other Mammalia	0	0	0	0	0	0
1.u. Quail (Coturnix coturnix)	14	14	0	0	0	0
1.v. Other birds (other <i>Aves</i>)	1 011	352	300	0	359	22
1.w. Reptiles (Reptilia)	40	0	0	0	40	0
1.x. Amphibians (Amphibia)	865	62	40	0	763	0
1.y. Fish (Pisces)	1 199	192	4	0	1 003	0
1.z. TOTAL	167 312	47 169	116 991	184	2 968	326

Note 1: Column 1.5 concerns only those Member countries of the Council of Europe which, at the beginning of the reporting period, are Parties to the Convention ETS 123. Thus an updated list of those countries has to be used when filling in this column.

Note 3: The number of re-used animals in column 1.7 should be excluded from the total in the column 1.2

Note 2: Only the white boxes need to be completed.

TABLE 2: NUMBER OF ANIMALS USED IN EXPERIMENTS FOR SELECTED PURPOSES

Purpose versus species

	2.1	2.2	2.3	2.4	2.5	2.6	2.7	2.8	2.9	2.10
	Species	Biological	Research and	Production and	Production and	Toxicological	Diagnosis of	Education and	Other	Total
	Species	studies of a	development of	quality control of	quality control of	and other safety	disease	training	Other	Total
		fundamenta	products and	products and	products and	evaluations	ansouse	uumng		
		l nature	devices for human	devices for	devices for	(including				
			medicine and	human medicine	veterinary	safety				
			dentistry and for	and dentistry	medicine	evaluation of				
			veterinary	·		products and				
			medicine			devices for				
			(excluding			human				
			toxicological and			medicine and				
			other safety			dentistry and				
			evaluations			for veterinary				
			counted in column 2.6)			medicine)				
2.a.	Mice	25 313	74 677	20 884	177	2 956	1 296	106	3 225	128 634
2.b.	Rats	5 019	2 949	131	232	3 167	0	422	0	11 920
2.c.	Guinea-Pigs	24	548	1 411	197	967	0	2	0	3 149
2.d.	Hamsters	0	117	0	0	0	0	0	0	117
2.e.	Other Rodents	47	0	0	0	0	0	0	60	107
2.f.	Rabbits	344	75	17 019	23	928	0	8	42	18 439
2.g.	Cats	0	2	0	0	0	10	0	0	12
2.h.	Dogs	6	56	0	0	0	0	12	11	85
2.i.	Ferrets	0	0	0	0	0	0	0	0	0
2.j.	Other Carnivores	0	0	0	0	0	0	0	0	0
2.k.	Horses, donkeys and cross	33	10	0	0	0	22	2	4	71
	breds									
2.1.	Pigs	265	255	73	0	0	0	189	36	818
2.m.	Goats	0	4	0	0	0	0	40	0	44
2.n.	Sheep	20	50	1	42	12	0	70	0	195
2.0.	Cattle	333	0	0	12	3	0	140	48	536
2.p.	Prosimians	0	0	0	0	0	0	0	0	0
2.q.	New World Monkeys	0	0	0	0	0	0	0	0	0
2.r.	Old World Monkeys	0	56	0	0	0	0	0	0	56
2.s.	Apes	0	0	0	0	0	0	0	0	0
2.t.	Other Mammals	0	0	0	0	0	0	0	0	0
2.u.	Quail	14	0	0	0	0	0	0	0	14
2.v.	Other birds	725	151	4	0	0	60	71	0	1 011
2.w.	Reptiles	40	0	0	0	0	0	0	0	40
2.x.	Amphibians	860	0	0	0	0	0	5	0	865
2.y.	Fish	876	180	0	0	143	0	0	0	1 199
2.z.	TOTAL	33 919	79 130	39 523	683	8 176	1 388	1 067	3 426	167 312

TABLE 3: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS

Products versus species

							•				
	3.1	3.2	3.3	3.4	3.5	3.6	3.7	3.8	3.9	3.10	3.11
	Species	Products/	Products/	Products/	Products/	Products/	Products/	Products/	Potential or	Other	Total
		substances or	substances	substances	substances	substances	substances	substances	actual	toxicological	
		devices for	used or	used or	used or	used or	used or	used or	contaminants in	or safety	
		human	intended to	intended to	intended to	intended to	intended to be	intended to be	the general	evaluations	
		medicine and	be used	be used	be used	be used	used mainly	used mainly	environment		
		dentistry and	mainly in	mainly in	mainly in	mainly as	as additives in	as additives in	which do not		
		for veterinary	agriculture	industry	the	cosmetics	food for	food for	appear in other		
		medicine			household	or toiletries	human	animal	columns		
	2.0						consumption	consumption			
3.a.	Mice	2 026	0	0	0	0	0	0	0	930	2 95
3.b.	Rats	1 415	0	0	0	0	0	0	0	1 752	3 16
3.c.	Guinea-Pigs	279	0	0	0	0	0	0	0	688	96
3.d.	Hamsters	0	0	0	0	0	0	0	0	0	
3.e.	Other Rodents	0	0	0	0	0	0	0	0	0	
3.f.	Rabbits	715	0	0	0	0	0	0	0	213	92
3.g.	Cats	0	0	0	0	0	0	0	0	0	
3.h.	Dogs	0	0	0	0	0	0	0	0	0	
3.i.	Ferrets	0	0	0	0	0	0	0	0	0	
3.j.	Other Carnivores	0	0	0	0	0	0	0	0	0	
3.k.	Horses, donkeys and cross breds	0	0	0	0	0	0	0	0	0	
3.1.	Pigs	0	0	0	0	0	0	0	0	0	
3.m.	Goats	0	0	0	0	0	0	0	0	0	
3.n.	Sheep	0	0	0	0	0	0	0	0	12	1
3.o.	Cattle	3	0	0	0	0	0	0	0	0	
3.p.	Prosimians	0	0	0	0	0	0	0	0	0	
3.q.	New World Monkeys	0	0	0	0	0	0	0	0	0	
3.r.	Old World Monkeys	0	0	0	0	0	0	0	0	0	
3.s.	Apes	0	0	0	0	0	0	0	0	0	
3.t.	Other Mammals	0	0	0	0	0	0	0	0	0	
3.u.	Quail	0	0	0	0	0	0	0	0	0	
3.v.	Other birds	0	0	0	0	0	0	0	0	0	
3.w.	Reptiles	0	0	0	0	0	0	0	0	0	
3.x.	Amphibians	0	0	0	0	0	0	0	0	0	
3.y.	Fish	0	0	0	0	0	0	0	0	143	14
3.z.	TOTAL	4 438	0	0	0	0	0	0	0	3 738	8 17

TABLE 4: NUMBER OF ANIMALS USED IN EXPERIMENTS FOR STUDIES ON HUMAN AND ANIMAL DISEASES

Main categories versus species

	4.1	4.2	4.3	4.4	4.5	4.6	4.7
	Species	Human cardiovascular	Human nervous and	Human cancer (excluding	Other human diseases	Studies specific to animal	Total
	r	diseases	mental disorders	evaluations of carcinogenic		diseases	
				hazards or risks)			
4.a.	Mice	1 275	3 407	15 919	45 266	95	65 962
4.b.	Rats	506	1 777	609	4 919	0	7 811
4.c.	Guinea-Pigs	0	0	0	905	0	905
4.d.	Hamsters	0	0	0	117	0	117
4.e.	Other Rodents	0	0	0	0	0	0
4.f.	Rabbits	53	31	89	294	0	467
4.g.	Cats	0	0	0	0	0	0
4.h.	Dogs	0	0	0	0	0	0
4.i.	Ferrets	0	0	0	0	0	0
4.j.	Other Carnivores	0	0	0	0	0	0
4.k.	Horses, donkeys and cross breds	0	0	0	0	0	0
4.1.	Pigs	106	0	0	292	0	398
4.m.	Goats	0	0	0	4	0	4
4.n.	Sheep	2	0	12	26	0	40
4.0.	Cattle	0	0	0	0	0	0
4.p.	Prosimians	0	0	0	0	0	0
4.q.	New World Monkeys	0	0	0	0	0	0
4.r.	Old World Monkeys	0	0	0	56	0	56
4.s.	Apes	0	0	0	0	0	0
4.t.	Other Mammals	0	0	0	0	0	0
4.u.	Quail	0	0	0	0	0	0
4.v.	Other birds	54	0	0	6	0	60
4.w.	Reptiles	0	0	0	0	0	0
4.x.	Amphibians	25	25	0	12	0	62
4.y.	Fish	0	0	0	0	0	0
4.z.	TOTAL	2 021	5 240	16 629	51 897	95	75 882

TABLE 5: NUMBER OF ANIMALS USED IN PRODUCTION AND QUALITY CONTROL OF PRODUCTS AND DEVICES FOR HUMAN MEDICINE AND DENTISTRY AND FOR VETERINARY MEDICINE

Regulatory requirements versus species

	5.1	5.2	5.3	5.4	5.5	5.6	5.7	5.8
	Species	National legislation	EC legislation	Member Country of Council	Other legislation	Any combination of	No regulatory	Total
		specific to a single EC	including European	of Europe (but not EC)		5.2/ 5.3/ 5.4/ 5.5	requirements	
		Member State	Pharmacopoeia	legislation				
		1)	(requirements)	2)				
5.a.	Mice	177	887	0	0	19 909	88	21 061
5.b.	Rats	131	0	0	232	0	0	363
5.c.	Guinea-Pigs	0	636	0	197	775	0	1 608
5.d.	Hamsters	0	0	0	0	0	0	0
5.e.	Other Rodents	0	0	0	0	0	0	0
5.f.	Rabbits	0	12 884	0	32	3 981	145	17 042
5.g.	Cats	0	0	0	0	0	0	0
5.h.	Dogs	0	0	0	0	0	0	0
5.i.	Ferrets	0	0	0	0	0	0	0
5.j.	Other Carnivores	0	0	0	0	0	0	0
5.k.	Horses, donkeys and cross breds	0	0	0	0	0	0	0
5.1.	Pigs	0	0	0	0	0	73	73
5.m.	Goats	0	0	0	0	0	0	0
5.n.	Sheep	21	22	0	0	0	0	43
5.o.	Cattle	12	0	0	0	0	0	12
5.p.	Prosimians	0	0	0	0	0	0	0
5.q.	New World Monkeys	0	0	0	0	0	0	0
5.r.	Old World Monkeys	0	0	0	0	0	0	0
5.s.	Apes	0	0	0	0	0	0	0
5.t.	Other Mammals	0	0	0	0	0	0	0
5.u.	Quail	0	0	0	0	0	0	0
5.v.	Other birds	4	0	0	0	0	0	4
5.w.	Reptiles	0	0	0	0	0	0	0
5.x.	Amphibians	0	0	0	0	0	0	0
5.y.	Fish	0	0	0	0	0	0	0
5.z.	TOTAL	345	14 429	0	461	24 665	306	40 206
Erron				Notes columns 5.2		tion imposing that the test		

Examples:

Footnotes:

5.2 – France is testing due to a UK (or FR) specific requirement

5.3 - UK is testing according to EC legislation

5.4 – Spain is testing due to a Hungarian requirement

5.5 – Sweden is testing due to a US specific requirement

5.6 - Germany is testing due to a Czech requirement (also an EC

requirement)

Note: columns 5.2 - 5.5 refer to the legislation imposing that the test be carried out and

not to the body which has issued the actual test method, guideline or protocol.

Example: a test required by French legislation and carried out in Belgium according to an

ISO protocol must be coded as a national (FR) legislative requirement and be

entered into column 5.2 in the tables submitted by Belgium.

- 1) EC Member States: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden, United Kingdom
- 2) Member Countries of Council of Europe (non-EC): Albania, Andorra, Bulgaria, Croatia, Cyprus, Czech Rep., Estonia, Hungary, Iceland, Latvia, Liechtenstein, Lithuania, Malta, Moldova, Norway, Poland, Romania, Russia, San Marino, Slovakia, Slovenia, Switzerland, 'the former Yugoslav Rep. of Macedonia', Turkey, Ukraine

NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS TABLE 6:

Regulatory requirements versus species

	6.1 Species	6.2 National legislation specific to a single EC Member State 1)	6.3 EC legislation including European Pharmacopoeia (requirements)	6.4 Member Country of Council of Europe (but not EC) legislation 2)	6.5 Other legislation	6.6 Any combination of 6.2/ 6.3/ 6.4/ 6.5	6.7 No regulatory requirements	6.8 Total
6.a.	Mice	0	1 595	0	1 060	60	241	2 956
6.b.	Rats	0	210	0	2 094	576	287	3 167
6.c.	Guinea-Pigs	0	204	0	763	0	0	967
6.d.	Hamsters	0	0	0	0	0	0	0
6.e.	Other Rodents	0	0	0	0	0	0	0
6.f.	Rabbits	0	595	0	213	77	43	928
6.g.	Cats	0	0	0	0	0	0	0
6.h.	Dogs	0	0	0	0	0	0	0
6.i.	Ferrets	0	0	0	0	0	0	0
6.j.	Other Carnivores	0	0	0	0	0	0	0
6.k.	Horses, donkeys and cross breds	0	0	0	0	0	0	0
6.1.	Pigs	0	0	0	0	0	0	0
6.m.	Goats	0	0	0	0	0	0	0
6.n.	Sheep	0	0	0	0	0	12	12
6.0.	Cattle	0	3	0	0	0	0	3
6.p.	Prosimians	0	0	0	0	0	0	0
6.q.	New World Monkeys	0	0	0	0	0	0	0
6.r.	Old World Monkeys	0	0	0	0	0	0	0
6.s.	Apes	0	0	0	0	0	0	0
6.t.	Other Mammals	0	0	0	0	0	0	0
6.u.	Quail	0	0	0	0	0	0	0
6.v.	Other birds	0	0	0	0	0	0	0
6.w.	Reptiles	0	0	0	0	0	0	0
6.x.	Amphibians	0	0	0	0	0	0	0
6.y.	Fish	0	0	0	143	0	0	143
6.z.	TOTAL	0	2 607	0	4 273	713	583	8 176

Examples:

6.2 – France is testing due to a UK (or FR) specific requirement

6.3 - UK is testing according to EC legislation

6.4 – Spain is testing due to a Hungarian requirement

6.5 – Sweden is testing due to a US specific requirement

6.6 - Germany is testing due to a Czech requirement (also an EC requirement)

Note:

columns 6.2 - 6.5 refer to the legislation imposing that the test be carried out and not to the body which has issued the actual test method, guideline or protocol.

a test required by French legislation and carried out in Belgium according to an Example:

ISO protocol must be coded as a national (FR) legislative requirement and be

entered into column 6.2 in the tables submitted by Belgium.

Footnotes:

EC Member States: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden, United Kingdom

Member Countries of Council of Europe (non-EC): Albania, Andorra, Bulgaria, Croatia, Cyprus, Czech Rep., Estonia, Hungary, Iceland, Latvia, Liechtenstein, Lithuania, Malta, Moldova, Norway, Poland, Romania, Russia, San Marino, Slovakia, Slovenia, Switzerland, 'the former Yugoslav Rep. of Macedonia', Turkey, Ukraine

TABLE 7: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS

Types of tests versus species

	7.1		7.2		7.3	7.4	7.5	7.6	7.7	7.8	7.9	7.10	7.11	7.12	7.13
	Species	Acute and s	ub-acute toxicity t	testing methods	Skin	Skin	Eye	Sub-	Carcino-	Develop-	Muta-	Repro-	Toxicity	Other	Total
	•		(including limit to		irritation	sensitisatio	irritation	chronic and	genicity	mental	genicit	ductive	to aquatic		
			_			n		chronic		toxicity	y	toxicity	vertebra-		
								toxicity					tes not		
													included		
													in other		
		7.0.1	7.2.2	7.2.2									columns		
		7.2.1. LD50,	7.2.2 Other lethal	7.2.3 Non lethal											
		LD50, LC50	methods	clinical signs											
		LC30	methods	methods											
7.a.	Mice	0	293	1 580	0	784	0	0	0	0	154	0	0	145	2 956
7.b.	Rats	0	726	229	104	0	0	1 596	0	0	12	0	0	500	3 167
7.c.	Guinea-Pigs	0	0	119	0	688	0	0	0	0	0	0	0	160	967
7.d.	Hamsters	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.e.	Other Rodents	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.f.	Rabbits	0	0	70	123	0	88	0	0	0	0	0	0	647	928
7.g.	Cats	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.h.	Dogs	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.i.	Ferrets	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.j.	Other Carnivores	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.k.	Horses, donkeys and cross breds	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.1.	Pigs	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.m.	Goats	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.n.	Sheep	0	0	0	0	0	0	0	0	0	0	0	0	12	12
7.o.	Cattle	0	0	3	0	0	0	0	0	0	0	0	0	0	3
7.p.	Prosimians	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.q.	New World Monkeys	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.r.	Old World Monkeys	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.s.	Apes	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.t.	Other Mammals	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.u.	Quail	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.v.	Other birds	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.w.	Reptiles	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.x.	Amphibians	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.y.	Fish	0	143	0	0	0	0	0	0	0	0	0	0	0	143
7.z.	TOTAL	0	1 162	2 001	227	1 472	88	1 596	0	0	166	0	0	1 464	8 176

TABLE 8: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS

Types of tests versus products

	8.1		8.2		8.3	8.4	8.5	8.6	8.7	8.8	8.9	8.10	8.11	8.12	8.13
	Products	meth	nd sub-acute tox ods (including li	mit test)	Skin irritation	Skin sensitisatio n	Eye irritation	Sub- chronic and chronic toxicity	Carcino genicity	Develop- mental toxicity	Muta- genicit y	Reproductive toxicity	Toxicity to aquatic vertebra- tes not included in other columns	Other	Total
		8.2.1. LD50, LC50	8.2.2 Other lethal methods	8.2.3 Non lethal clinical signs methods											
8.a.	Products/substances or devices for human medicine and dentistry and for veterinary medicine	0	381	2 001	62	8	0	662	0	0	6	0	0	1 318	4 438
8.b.	Products/substances used or intended to be used mainly in agriculture	0	0	0	0	0	0	0	0	0	0	0	0	0	0
8.c.	Products/substances used or intended to be used mainly in industry	0	0	0	0	0	0	0	0	0	0	0	0	0	0
8.d.	Products/substances used or intended to be used mainly in the household	0	0	0	0	0	0	0	0	0	0	0	0	0	0
8.e.	Products/substances used or intended to be used mainly as cosmetics or toiletries	0	0	0	0	0	0	0	0	0	0	0	0	0	0
8.f.	Products/substances used or intended to be used mainly as additives in food for human consumption	0	0	0	0	0	0	0	0	0	0	0	0	0	0
8.g.	Products/substances used or intended to be used mainly as additives in food for animal consumption	0	0	0	0	0	0	0	0	0	0	0	0	0	0
8.h.	Potential or actual contaminants in the general environment which do not appear in other columns	0	0	0	0	0	0	0	0	0	0	0	0	0	0
8.i.	Other toxicological or safety evaluations	0	781	0	165	1 464	88	934	0	0	160	0	0	146	3 738
8.j.	TOTAL	0	1 162	2 001	227	1 472	88	1 596	0	0	166	0	0	1 464	8 176

BELGIUM

Statistical data submitted

The statistical data have been submitted by the "SPF Santé Publique, Sécurité de la Chaine Alimentaire et Environnement" (Federal Public Service of Public Health, Food Chain Safety and Environment).

Comments of the Belgian authorities

ANIMALS USED FOR EXPERIMENTAL PURPOSES

STATISTICS ON USE IN BELGIUM IN 2005

1. Laboratories

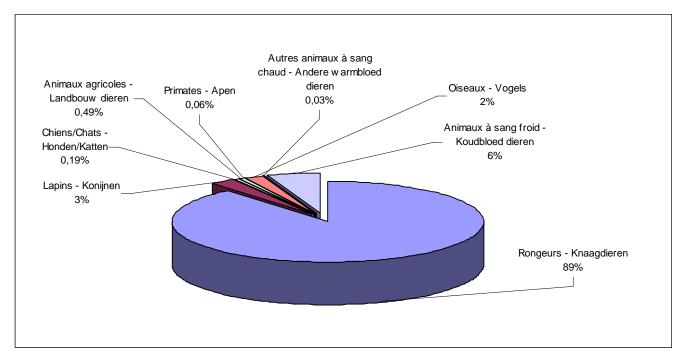
At the end of 2005, there were 390 approved laboratories in operation which, pursuant to Article 15 of the Royal Decree of 14 November 1993 on the protection of animals used for experimental purposes, provided data on their use of animals for experiments. As in previous years, 25% of laboratories used no animals.

In 2005, four laboratory approvals were withdrawn at the request of the head of the laboratory because it had ceased operations; five new approvals were issued for laboratories and one for a supplier of animals for experimental purposes.

2. Number of animals used in experiments

In all 718 976 animals were used. Of the various species used, rodents and rabbits accounted for 92%, fish, reptiles and amphibians accounted for 6% and birds for 2% of the total.

Dogs, cats and primates accounted respectively for 0.19%, 0.01% and 0.06% of the animals used in 2005 (Figure 1: Breakdown of species used in experiments).



Animaux agricoles – agricultural animals; Primates – primates; Autres animaux à sang chaud – other warm-blooded animals; Oiseaux – birds; Animaux à sang froid – cold-blooded animals; Rongeurs – rodents; Lapins – rabbits; Chiens/chats – dogs/cats

A comparison of the figures for 2005 with those for previous years (*Table 1: Trend in the number of animals used in experiments*), shows an increase in the total number of animals of 1.44% over 2004. That increase was due mainly to greater use of fish (+ 13 391, 65%), birds (+ 2 849, 26%), mice (+ 5 315, 1.1%) and, to a lesser extent, dogs (+ 201, 27%) and ferrets (+ 52, 51%). There was a substantial drop in the number of monkeys (- 137, 23%), rats (- 12 710, 11%), other rodents (- 1 661, 42%) and cats (- 103, 56%).

Table 1: Trend in the number of animals used in experiments

	2005	2004	2003	2002	2001
Mice	488125	482810	430251	460487	436266
Rats	106483	119193	128284	116340	112040
Guinea pigs	39530	38781	40510	34305	40204
Hamsters	1874	1688	2590	2645	3163
Other rodents	2260	3921	11332	16670	12693
Rabbits	21159	18577	18714	10805	14631
Total rodents and rabbits	659431	664970	631681	641252	618997
Cats	81	184	90	100	75
Dogs	1295	1014	1000	1071	1036
Ferrets	154	102	36	20	20
Other carnivores	0	0	0	0	0
Total carnivores	1530	1300	1126	1191	1131
Horses, donkeys and cross-breds	108	65	93	138	102
Pigs	1876	2272	2637	3587	4079
Goats	157	125	114	102	217
Sheep	445	495	339	524	492
Cattle	944	982	1055	1135	714
Total ungulates	3530	3939	4238	5486	5604
Prosimians	0	0	0	0	0
New world monkeys	0	7	7	20	21
Old world monkeys	449	579	281	547	689
Apes	0	0	0	0	0
Total primates	449	586	288	567	710
Other mammals	59	44	22	8	0
Total mammals	664999	670839	637355	648504	626442
Quails	425	350	514	326	134
Other birds	13266	10492	12499	20026	8711
Total birds	13691	10842	13013	20352	8845
Reptiles	144	129	30	15	95
Amphibians	6177	6362	1803	1601	2460
Fish	33965	20574	24363	24619	17375
Total cold-blooded animals	40286	27065	26196	26235	19930
TOTAL ANIMALS	718976	708746	676564	695.091	655.217

The following graph (Figure 2: Trend in the number of animals used since 1997) clearly shows that the number of animals used in Belgian laboratories fell between 1997 and 2005 (by 16%), even though there were some unrepresentative annual fluctuations.

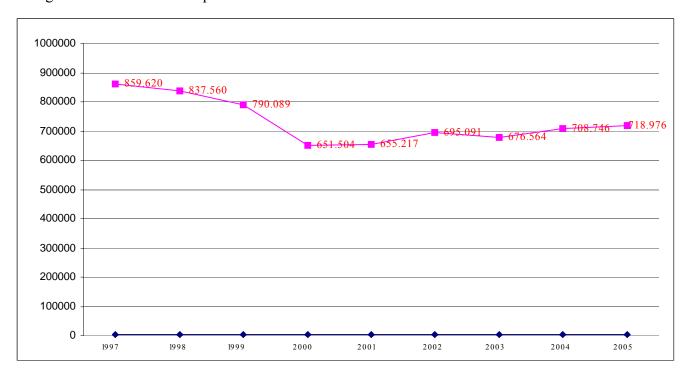


Figure 2: Trend in the number of animals used since 1997

3. Experiments carried out

In descending order, animals were used mainly for research and to develop products and devices used in human and veterinary medicine (33% of the animals used), basic research studies (29%) and tests on the production and quality control of such products and devices (24%) (*Figure 3: Breakdown of the experimental fields*). There has been a steady rise in the number of animals used for basic research and the figure in 2005 was the highest ever for this category. As regards production and quality control tests and toxicology tests, 98% and 90% respectively of the animals were used to meet legal requirements.

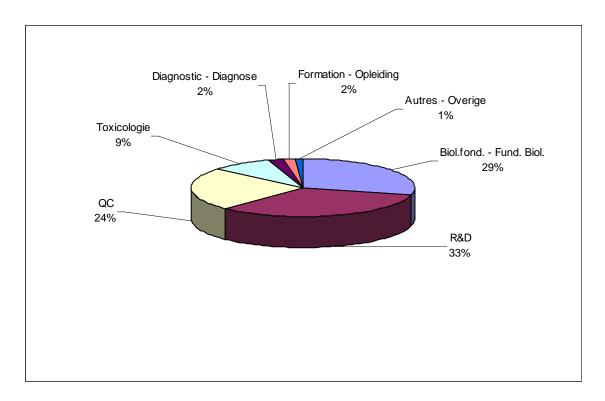


Figure 3: Breakdown of the experimental fields

 $\label{eq:diagnostic} Diagnostic - diagnostics; Formation - training; Autres - other; Biol. Fond. - basic biology; R\&D - research and development; QC - quality control; Toxicologie - toxicology$

The following diagram (Figure 4: Breakdown of experimental fields by the animals most used) shows that, of the animals most used, rats and mice are used mainly for basic research and the development of products and material for medicine (65%) and for safety tests (22%).

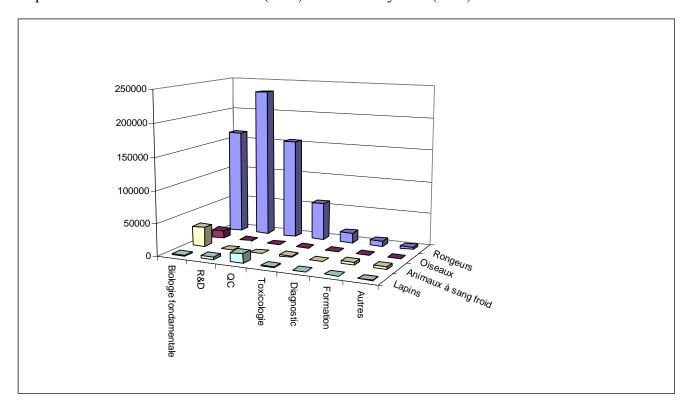


Figure 4: Breakdown of experimental fields by the animals most used

Biologie fondamentale – basic biology; R&D – research and development; QC – quality control; Toxicologie – toxicology; Diagnostic – diagnostics; Formation – training; Autres – other; Lapins – rabbits; Animaux à sang froid – cold-blooded animals; Oiseaux – birds; Rongeurs – rodents.

As regards the other species, 92% of primates and 78% of dogs were used in toxicology tests for safety.

The use of primates is still linked to the World Health Organisation programme to eradicate poliomyelitis worldwide, a programme for which the bulk of the oral polio vaccine is produced in Belgium. Primates have not been used to produce the vaccine since 2003 and neurovirulence tests on types of vaccine strain are now carried out solely on mice rather then primates, a method which recently became part of international law.

The fields where use has increased significantly since 2004 are training (by 5 166, 71%), medical diagnosis (by 7 475, 88%) and toxicology tests (by 15 026, 31%).

Toxicology and safety tests account for 9% of the animals used in experiments in 2005; 90% of the animals used in toxicology tests were used in safety trials required by laws and regulations (*Figure 5: Proportion of quality control and toxicology tests imposed by law*).

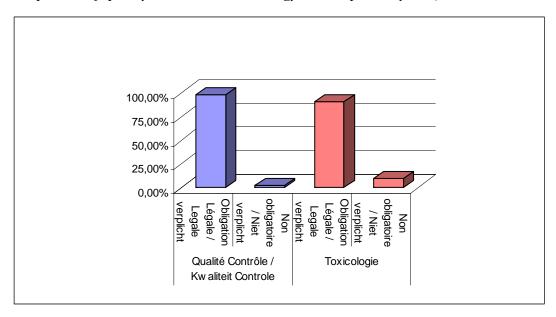


Figure 5: Proportion of quality control and toxicology tests imposed by law

Obligation légale – legal requirement; Non obligatoire – not compulsory; Qualité Contrôle – quality control; Toxicologie –toxicology.

4. Origin of animals used in experiments

The Royal Decree of 14 November 1993 on the protection of animals used for experimental purposes lays down the list of animals which must come from specifically approved suppliers. In 2005, 91% of the animals used in experiments were on that list. Of these, 96% came from approved suppliers in Belgium, other countries of the European Union and members of the Council of Europe.

Animals belonging to agricultural species and other animals, including cold-blooded animals, do not appear on the list in the Royal Decree of 14 November 1993. They come from suppliers which meet the conditions laid down by the legislation in force for such establishments.

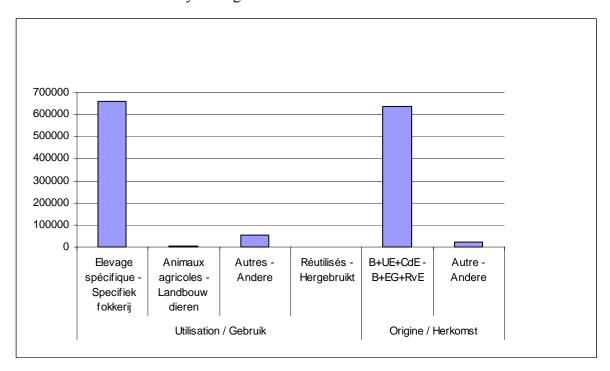


Figure 6: Origin of animals used in experiments

Elevage spécifique – specially bred; Animaux agricoles – agricultural animals; Autres – other; Réutilisés – reused; B+UE+CdE – B+EU+CoE; Utilsiation – use; Origine – origin

TABLE 1: NUMBER OF ANIMALS USED IN RELATION TO THEIR PLACE OF ORIGIN

Origin versus species

	1.1	1.2	1.3	1.4	1.5	1.6	1.7
	Species	Total	Animals coming from registered	Animals coming from	Animals coming from	Animals coming from	Re-used animals
	1		breeding or supplying	elsewhere in the EC	Member Countries of the	other origins	
			establishments within the reporting		Council of Europe which are		
			country		parties to the Convention ETS		
					123 (excluding EC Member		
					States)		
1.a.	Mice (Mus musculus)	488125	166973	298054	1079	22019	
1.b.	Rats (Rattus norvegicus)	106483	19125	80233	6535	590	
1.c.	Guinea-Pigs (Cavia porcellus)	39530	5352	34178	0	0	
1.d.	Hamsters (Mesocricetus)	1874	69	1773	0	32	
1.e.	Other Rodents (other <i>Rodentia</i>)	2260					
1.f.	Rabbits (Oryctolagus cuniculus)	21159	18347	2806	0	6	536
1.g.	Cats (Felis catus)	81	49	32	0	0	78
1.h.	Dogs (Canis familiaris)	1295	82	898	23	292	475
1.i.	Ferrets (Mustela putorius furo)	154	0	154	0	0	0
1.j.	Other Carnivores (other Carnivora)	0					
1.k.	Horses, donkeys and cross breds (Equidae)	108					
1.1.	Pigs (Sus)	1876					
1.m.	Goats (Capra)	157					
1.n.	Sheep (Ovis)	445					
1.o.	Cattle (Bos)	944					
1.p.	Prosimians (<i>Prosimia</i>)	0	0	0	0	0	0
1.q.	New World Monkeys (Ceboidea)	0	0	0	0	0	7
1.r.	Old World Monkeys (Cercopithecoidea)	449	0	37	0	412	22
1.s.	Apes (Hominoidea)	0	0	0	0	0	0
1.t.	Other Mammals (other Mammalia)	59					
1.u.	Quail (Coturnix coturnix)	425	421	0	0	4	
1.v.	Other birds (other Aves)	13266					
1.w.	Reptiles (Reptilia)	144					
1.x.	Amphibians (Amphibia)	6177					
1.y.	Fish (Pisces)	33965					
1.z.	TOTAL	718976					

Note 1: Column 1.5 concerns only those Member Countries of the Council of Europe which, at the beginning of the reporting period, are Parties to the Convention ETS 123. Thus an updated list of those countries has to be used when filling in this column.

Note 2: Only the white boxes need to be completed.

Note 3: The number of re-used animals in column 1.7 should be excluded from the total in the column 1.2

TABLE 2: NUMBER OF ANIMALS USED IN EXPERIMENTS FOR SELECTED PURPOSES

Purpose versus species

	2.1	2.2	2.3	2.4	2.5	2.6	2.7	2.8	2.9	2.10
	Species	Biological	Research and	Production and	Production and	Toxicological	Diagnosis of	Education and	Other	Total
	Species	studies of a	development of	quality control of	quality control of	and other safety	disease	training	Other	Total
		fundamenta	products and	products and	products and	evaluations	aisease			
		1 nature	devices for human	devices for	devices for	(including				
			medicine and	human medicine	veterinary	safety				
			dentistry and for	and dentistry	medicine	evaluation of				
			veterinary			products and				
			medicine			devices for				
			(excluding			human				
			toxicological and			medicine and				
			other safety evaluations			dentistry and				
			counted in column			for veterinary medicine)				
			2.6)			medicine)				
2.a.	Mice	142620	168987	114435	6487	31740	15303	5518	3035	488125
2.b.	Rats	20078	56836	13598	131	12960	487	1843	550	106483
2.c.	Guinea-Pigs	247	5497	18039	1006	14190	26	525	0	39530
2.d.	Hamsters	131	1	0	1660	0	0	34	48	1874
2.e.	Other Rodents	411	1697	0	0	142	0	0	10	2260
2.f.	Rabbits	1326	3888	14276	329	1095	0	84	161	21159
2.g.	Cats	49	0	0	32	0	0	0	0	81
2.h.	Dogs	115	104	0	38	1018	7	13	0	1295
2.i.	Ferrets	0	154	0	0	0	0	0	0	154
2.j.	Other Carnivores	0	0	0	0	0	0	0	0	0
2.k.	Horses, donkeys and cross	28	27	15	2	0	1	31	4	108
	breds									
2.1.	Pigs	1197	144	21	187	95	16	113	103	1876
2.m.	Goats	26	54	0	40	0	0	32	5	157
2.n.	Sheep	177	123	0	34	24	0	2	85	445
2.0.	Cattle	97	136	0	484	15	83	17	112	944
2.p.	Prosimians	0	0	0	0	0	0	0	0	0
2.q.	New World Monkeys	0	0	0	0	0	0	0	0	0
2.r.	Old World Monkeys	37	0	0	0	412	0	0	0	449
2.s.	Apes	0	0	0	0	0	0	0	0	0
2.t.	Other Mammals	28	31	0	0	0	0	0	0	59
2.u.	Quail	421	0	0	0	0	0	4	0	425
2.v.	Other birds	11546	1269	165	36	238	0	2	10	13266
2.w.	Reptiles	144	0	0	0	0	0	0	0	144
2.x.	Amphibians	5071	0	0	0	0	30	1076	0	6177
2.y.	Fish	25466	0	0	0	1769	0	3130	3600	33965
2.z.	TOTAL	209215	238948	160549	10466	63698	15953	12424	7723	718976

TABLE 3: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS

Products versus species

	3.1	3.2	3.3	3.4	3.5	3.6	3.7	3.8	3.9	3.10	3.11
	Species	Products/	Products/	Products/	Products/	Products/	Products/	Products/	Potential or	Other toxico-	Total
		substances or	substances	substances	substances	substances	substances	substances	actual contami-	logical or	
		devices for	used or	used or	used or	used or	used or	used or	nents in the	safety	
		human	intended to	intended to	intended to	intended to	intended to be	intended to be	general envi-	evaluations	
		medicine and	be used	be used	be used	be used	used mainly	used mainly	ronment which		
		dentistry and	mainly in	mainly in	mainly in	mainly as	as additives in	as additives in	do not appear in		
		for veterinary	agriculture	industry	the	cosmetics	food for	food for	other columns		
		medicine			household	or toiletries	human	animal			
_	7.0						consumption	consumption			2.7
3.a.	Mice	30371	50	50	0	0	0	0	1254	15	31740
3.b.	Rats	12260	0	0	0	0	0	0	0	700	12960
3.c.	Guinea-Pigs	14190	0	0	0	0	0	0	0	0	14190
3.d.	Hamsters	0	0	0	0	0	0	0	0	0	0
3.e.	Other Rodents	0	0	0	0	0	0	0	142	0	142
3.f.	Rabbits	1095	0	0	0	0	0	0	0	0	1095
3.g.	Cats	0	0	0	0	0	0	0	0	0	0
3.h.	Dogs	1018	0	0	0	0	0	0	0	0	1018
3.i.	Ferrets	0	0	0	0	0	0	0	0	0	0
3.j.	Other Carnivores	0	0	0	0	0	0	0	0	0	0
3.k.	Horses, donkeys and cross breds	0	0	0	0	0	0	0	0	0	0
3.1.	Pigs	80	0	0	0	0	0	0	0	15	95
3.m.	Goats	0	0	0	0	0	0	0	0	0	0
3.n.	Sheep	24	0	0	0	0	0	0	0	0	24
3.o.	Cattle	0	0	0	0	0	0	0	0	15	15
3.p.	Prosimians	0	0	0	0	0	0	0	0	0	0
3.q.	New World Monkeys	0	0	0	0	0	0	0	0	0	0
3.r.	Old World Monkeys	412	0	0	0	0	0	0	0	0	412
3.s.	Apes	0	0	0	0	0	0	0	0	0	0
3.t.	Other Mammals	0	0	0	0	0	0	0	0	0	0
3.u.	Quail	0	0	0	0	0	0	0	0	0	0
3.v.	Other birds	118	0	0	0	0	0	0	120	0	238
3.w.	Reptiles	0	0	0	0	0	0	0	0	0	0
3.x.	Amphibians	0	0	0	0	0	0	0	0	0	0
3.y.	Fish	275	510	0	0	0	0	0	444	540	1769
3.z.	TOTAL	59843	560	50	0	0	0	0	1960	1285	63698

TABLE 4: NUMBER OF ANIMALS USED IN EXPERIMENTS FOR STUDIES ON HUMAN AND ANIMAL DISEASES

Main categories versus species

	4.1	4.2	4.3	4.4	4.5	4.6	4.7
	Species	Human cardiovascular	Human nervous and	Human cancer (excluding	Other human diseases	Studies specific to animal	Total
	-	diseases	mental disorders	evaluations of carcinogenic		diseases	
				hazards or risks)			
4.a.	Mice	5754	62251	46356	193220	9749	317330
4.b.	Rats	1845	29488	2602	41694	119	75748
4.c.	Guinea-Pigs	233	2134	0	15491	5	17863
4.d.	Hamsters	0	0	0	70	0	70
4.e.	Other Rodents	36	585	0	846	198	1665
4.f.	Rabbits	260	5	18	219	321	823
4.g.	Cats	0	0	0	0	0	0
4.h.	Dogs	56	16	0	121	2	195
4.i.	Ferrets	0	0	0	154	0	154
4.j.	Other Carnivores	0	0	0	0	0	0
4.k.	Horses, donkeys and cross breds	0	0	0	0	28	28
4.1.	Pigs	71	0	0	116	286	473
4.m.	Goats	0	0	0	60	0	60
4.n.	Sheep	39	0	0	75	0	114
4.o.	Cattle	4	0	0	0	136	140
4.p.	Prosimians	0	0	0	0	0	0
4.q.	New World Monkeys	0	0	0	0	0	0
4.r.	Old World Monkeys	0	0	0	25	0	25
4.s.	Apes	0	0	0	0	0	0
4.t.	Other Mammals	6	0	3	25	0	34
4.u.	Quail	0	0	0	0	0	0
4.v.	Other birds	0	0	0	211	1724	1935
4.w.	Reptiles	0	0	0	0	0	0
4.x.	Amphibians	9	0	0	3	0	12
4.y.	Fish	0	0	0	0	1000	1000
4.z.	TOTAL	8313	94479	48979	252330	13568	417669

TABLE 5: NUMBER OF ANIMALS USED IN PRODUCTION AND QUALITY CONTROL OF PRODUCTS AND DEVICES FOR HUMAN MEDICINE AND DENTISTRY AND FOR VETERINARY MEDICINE

Regulatory requirements versus species

	5.1	5.2	5.3	5.4	5.5	5.6	5.7	5.8
	Species	National legislation	EC legislation	Member Country of Council	Other legislation	Any combination of	No regulatory	Total
		specific to a single EC	including European	of Europe (but not EC)		5.2/ 5.3/ 5.4/ 5.5	requirements	
		Member State	Pharmacopoeia	legislation				
		1)	(requirements)	2)				
5.a.	Mice	0	26663	0	9365	83891	1003	120922
5.b.	Rats	0	294	0	1385	9621	2429	13729
5.c.	Guinea-Pigs	0	2534	0	4092	12410	9	19045
5.d.	Hamsters	0	840	0	0	820	0	1660
5.e.	Other Rodents	0	0	0	0	0	0	0
5.f.	Rabbits	0	81	0	219	14281	24	14605
5.g.	Cats	0	26	0	0	6	0	32
5.h.	Dogs	0	22	0	0	16	0	38
5.i.	Ferrets	0	0	0	0	0	0	0
5.j.	Other Carnivores	0	0	0	0	0	0	0
5.k.	Horses, donkeys and cross breds	0	0	0	2	0	15	17
5.1.	Pigs	0	82	0	0	105	21	208
5.m.	Goats	0	0	0	0	40	0	40
5.n.	Sheep	0	2	0	0	32	0	34
5.o.	Cattle	0	484	0	0	0	0	484
5.p.	Prosimians	0	0	0	0	0	0	0
5.q.	New World Monkeys	0	0	0	0	0	0	0
5.r.	Old World Monkeys	0	0	0	0	0	0	0
5.s.	Apes	0	0	0	0	0	0	0
5.t.	Other Mammals	0	0	0	0	0	0	0
5.u.	Quail	0	0	0	0	0	0	0
5.v.	Other birds	0	201	0	0	0	0	201
5.w.	Reptiles	0	0	0	0	0	0	0
5.x.	Amphibians	0	0	0	0	0	0	0
5.y.	Fish	0	0	0	0	0	0	0
5.z.	TOTAL	0	31229	0	15063	121222	3501	171015
	unlage 52 Enomos is tosting due			Notes columns 5.2		tion imposing that the test		

Examples:

Footnotes:

5.2 – France is testing due to a UK (or FR) specific requirement

5.3 - UK is testing according to EC legislation

5.4 – Spain is testing due to a Hungarian requirement

5.5 – Sweden is testing due to a US specific requirement

5.6 - Germany is testing due to a Czech requirement (also an EC

requirement)

Note: columns 5.2 - 5.5 refer to the legislation imposing that the test be carried out and

 $not \ to \ the \ body \ which \ has \ is sued \ the \ actual \ test \ method, \ guideline \ or \ protocol.$

Example: a test required by French legislation and carried out in Belgium according to an

ISO protocol must be coded as a national (FR) legislative requirement and be

entered into column 5.2 in the tables submitted by Belgium.

1) EC Member States: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden, United Kingdom

2) Member Countries of Council of Europe (non-EC): Albania, Andorra, Bulgaria, Croatia, Cyprus, Czech Rep., Estonia, Hungary, Iceland, Latvia, Liechtenstein, Lithuania, Malta, Moldova, Norway, Poland, Romania, Russia, San Marino, Slovakia, Slovenia, Switzerland, 'the former Yugoslav Rep. of Macedonia', Turkey, Ukraine

TABLE 6: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS

Regulatory requirements versus species

	6.1 Species	6.2 National legislation specific to a single EC Member State 1)	6.3 EC legislation including European Pharmacopoeia (requirements)	6.4 Member Country of Council of Europe (but not EC) legislation 2)	6.5 Other legislation	6.6 Any combination of 6.2/6.3/6.4/6.5	6.7 No regulatory requirements	6.8 Total
6.a.	Mice	0	3234	0	3180	21142	4184	31740
6.b.	Rats	0	0	0	640	11501	819	12960
6.c.	Guinea-Pigs	0	40	0	403	13747	0	14190
6.d.	Hamsters	0	0	0	0	0	0	0
6.e.	Other Rodents	0	0	0	0	0	142	142
6.f.	Rabbits	0	12	0	0	1069	14	1095
6.g.	Cats	0	0	0	0	0	0	0
6.h.	Dogs	0	0	0	0	1018	0	1018
6.i.	Ferrets	0	0	0	0	0	0	0
6.j.	Other Carnivores	0	0	0	0	0	0	0
6.k.	Horses, donkeys and cross breds	0	0	0	0	0	0	0
6.1.	Pigs	0	80	0	0	0	15	95
6.m.	Goats	0	0	0	0	0	0	0
6.n.	Sheep	0	24	0	0	0	0	24
6.0.	Cattle	0	0	0	15	0	0	15
6.p.	Prosimians	0	0	0	0	0	0	0
6.q.	New World Monkeys	0	0	0	0	0	0	0
6.r.	Old World Monkeys	0	0	0	0	412	0	412
6.s.	Apes	0	0	0	0	0	0	0
6.t.	Other Mammals	0	0	0	0	0	0	0
6.u.	Quail	0	0	0	0	0	0	0
6.v.	Other birds	0	82	0	0	0	156	238
6.w.	Reptiles	0	0	0	0	0	0	0
6.x.	Amphibians	0	0	0	0	0	0	0
6.y.	Fish	230	0	0	590	275	674	1769
6.z.	TOTAL	230	3472	0	4828	49164	6004	63698

Examples:

6.2 – France is testing due to a UK (or FR) specific requirement

6.3 - UK is testing according to EC legislation

6.4 – Spain is testing due to a Hungarian requirement

6.5 – Sweden is testing due to a US specific requirement

6.6 – Germany is testing due to a Czech requirement (also an EC requirement)

Note:

columns 6.2 - 6.5 refer to the legislation imposing that the test be carried out and

not to the body which has issued the actual test method, guideline or protocol.

Example: a test required by French legislation and carried out in Belgium according to an

ISO protocol must be coded as a national (FR) legislative requirement and be

entered into column 6.2 in the tables submitted by Belgium.

Footnotes:

1) EC Member States: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden, United Kingdom

2) Member Countries of Council of Europe (non-EC): Albania, Andorra, Bulgaria, Croatia, Cyprus, Czech Rep., Estonia, Hungary, Iceland, Latvia, Liechtenstein, Lithuania, Malta, Moldova, Norway, Poland, Romania, Russia, San Marino, Slovakia, Slovenia, Switzerland, 'the former Yugoslav Rep. of Macedonia', Turkey, Ukraine

TABLE 7: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS

Types of tests versus species

	7.1		7.2		7.3	7.4	7.5	7.6	7.7	7.8	7.9	7.10	7.11	7.12	7.13
	Species	Acute and si	ub-acute toxicity	testing methods	Skin	Skin	Eye	Sub-	Carcino-	Develop-	Muta-	Repro-	Toxicity	Other	Total
	(including limit test)				irritation	sensitisatio	irritation	chronic and	genicity	mental	genicit	ductive	to aquatic		
						n		chronic		toxicity	У	toxicity	vertebra-		
								toxicity					tes not		
													included in other		
													columns		
		7.2.1.	7.2.2	7.2.3									Columns		
		LD50,	Other lethal	Non lethal											
		LC50	methods	clinical signs											
				methods											
7.a.	Mice	1534	15	24673	0	0	0	1720	854	457	1611	100	0	776	31740
7.b.	Rats	0	60	5297	0	0	0	1718	1604	1657	531	326	0	1767	12960
7.c.	Guinea-Pigs	0	0	14030	0	160	0	0	0	0	0	0	0	0	14190
7.d.	Hamsters	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.e.	Other Rodents	0	142	0	0	0	0	0	0	0	0	0	0	0	142
7.f.	Rabbits	0	0	169	18	9	12	0	0	814	0	0	0	73	1095
7.g.	Cats	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.h.	Dogs	0	0	474	0	0	0	215	0	0	0	0	0	329	1018
7.i.	Ferrets	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.j.	Other Carnivores	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.k.	Horses, donkeys and cross	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	breds								_	_			0	0.5	0.5
7.1.	Pigs	0	0	0	0	0	0	0	0	0	0	0	0	95	95
7.m.	Goats	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.n.	Sheep	0	0	0	0	0	0	0	0	0	0	0	0	24	24
7.0.	Cattle	0	0	0	0	0	0	0	0	0	0	0	0	15	15
7.p.	Prosimians	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.q.	New World Monkeys	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.r.	Old World Monkeys	0	0	412	0	0	0	0	0	0	0	0	0	0	412
7.s.	Apes	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.t.	Other Mammals	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.u.	Quail	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.v.	Other birds	0	100	0	0	0	0	0	0	0	0	0	0	138	238
7.w.	Reptiles	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.x.	Amphibians	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.y.	Fish	1298	0	0	0	0	0	76	0	0	0	0	0	395	1769
7.z.	TOTAL	2832	317	45055	18	169	12	3729	2458	2928	2142	426	0	3612	63698

TABLE 8: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS

Types of tests versus products

	8.1		8.2		8.3	8.4	8.5	8.6	8.7	8.8	8.9	8.10	8.11	8.12	8.13
	Products	meth	nd sub-acute tox ods (including li	mit test)	Skin irritation	Skin sensitisatio n	Eye irritation	Sub- chronic and chronic toxicity	Carcino genicity	Develop- mental toxicity	Muta- genicit y	Reproductive toxicity	Toxicity to aquatic vertebra- tes not included in other columns	Other	Total
		8.2.1. LD50, LC50	8.2.2 Other lethal methods	8.2.3 Non lethal clinical signs methods											
8.a.	Products/substances or devices for human medicine and dentistry and for veterinary medicine	1534	0	43801	18	169	12	3013	2458	2622	2142	426	1669	1788	59652
8.b.	Products/substances used or intended to be used mainly in agriculture	390	0	0	0	0	0	0	0	0	0	0	0	0	390
8.c.	Products/substances used or intended to be used mainly in industry	0	0	0	0	0	0	0	0	0	0	0	0	0	0
8.d.	Products/substances used or intended to be used mainly in the household	0	0	0	0	0	0	0	0	0	0	0	0	0	0
8.e.	Products/substances used or intended to be used mainly as cosmetics or toiletries	0	0	0	0	0	0	0	0	0	0	0	0	0	0
8.f.	Products/substances used or intended to be used mainly as additives in food for human consumption	0	0	0	0	0	0	0	0	0	0	0	0	0	0
8.g.	Products/substances used or intended to be used mainly as additives in food for animal consumption	0	0	0	0	0	0	0	0	0	0	0	0	0	0
8.h.	Potential or actual contaminants in the general environment which do not appear in other columns	368	317	0	0	0	0	76	0	0	0	0	0	155	916
8.i.	Other toxicological or safety evaluations	540	0	1254	0	0	0	640	0	306	0	0	0	0	2740
8.j.	TOTAL	2832	317	45055	18	169	12	3729	2458	2928	2142	426	1669	1943	63698

CYPRUS

Statistical data submitted

The statistical data have been submitted by "Veterinary Services of the Republic of Cyprus".

Remark: data are reported in table 1, 2 and 4 only.

Comments of the Cyprus authorities

The Director of the Veterinary Services of the Republic of Cyprus is empowered by Law to regulate all activities that relate to the use of experimental animals. At present, within the areas under the control of the Republic, only rodents (mice) are used in animal experimentation. These primarily include genetic models for various diseases or processes with main emphasis on Central Nervous System complications and development.

These activities began to take place in Cyprus in March 2003 and are all carried out in one research establishment, the Cyprus Institute of Neurology and Genetics (www.cing.ac.cy).

The Veterinary Services are satisfied that the animals are kept in a very rigorously monitored, pathogen-free environment (monitored according to FELASA guidelines). No outbreak of all pathogens tested has been observed. We are also satisfied that the principles of the three Rs are duly adhered to.

Dr. Giorgos Neophytou

Director of Veterinary Services

TABLE 1: NUMBER OF ANIMALS USED IN RELATION TO THEIR PLACE OF ORIGIN

Origin versus species

	1.1 Species	1.2 Total	1.3 Animals coming from registered breeding or supplying establishments within the reporting country	1.4 Animals coming from elsewhere in the EC	1.5 Animals coming from Member Countries of the Council of Europe which are parties to the Convention ETS 123 (excluding EC Member States)	1.6 Animals coming from other origins	1.7 Re-used animals
1.a.	Mice (Mus musculus)	967	930	12		25	
1.b.	Rats (Rattus norvegicus)	0					
1.c.	Guinea-Pigs (Cavia porcellus)	0					
1.d.	Hamsters (Mesocricetus)	0					
1.e.	Other Rodents (other Rodentia)						
1.f.	Rabbits (Oryctolagus cuniculus)	0					
1.g.	Cats (Felis catus)	0					
1.h.	Dogs (Canis familiaris)	0					
1.i.	Ferrets (Mustela putorius furo)	0					
1.j.	Other Carnivores (other Carnivora)						
1.k.	Horses, donkeys and cross breds (Equidae)						
1.1.	Pigs (Sus)						
1.m.	Goats (Capra)						
1.n.	Sheep (Ovis)						
1.o.	Cattle (Bos)						
1.p.	Prosimians (<i>Prosimia</i>)	0					
1.q.	New World Monkeys (Ceboidea)	0					
1.r.	Old World Monkeys (Cercopithecoidea)	0					
1.s.	Apes (Hominoidea)	0					
1.t.	Other Mammals (other Mammalia)						
1.u.	Quail (Coturnix coturnix)	0					
1.v.	Other birds (other Aves)						
1.w.	Reptiles (Reptilia)						
1.x.	Amphibians (Amphibia)						
1.y.	Fish (Pisces)						
1.z.	TOTAL	967					

Note 1: Column 1.5 concerns only those Member Countries of the Council of Europe which, at the beginning of the reporting period, are Parties to the Convention ETS 123. Thus an updated list of those countries has to be used when filling in this column.

Note 2: Only the white boxes need to be completed.

Note 3: The number of re-used animals in column 1.7 should be excluded from the total in the column 1.2

TABLE 2: NUMBER OF ANIMALS USED IN EXPERIMENTS FOR SELECTED PURPOSES

Purpose versus species

	2.1 Species	2.2 Biologic al studies of a fundame ntal nature	Research and development of products and devices for human medicine and dentistry and for veterinary medicine (excluding toxicological and	2.4 Production and quality control of products and devices for human medicine and dentistry	2.5 Production and quality control of products and devices for veterinary medicine	2.6 Toxicological and other safety evaluations (including safety evaluation of products and devices for human medicine and	2.7 Diagnosis of disease	2.8 Education and training	2.9 Other	2.10 Total
			other safety evaluations counted in column			dentistry and for veterinary medicine)				
			2.6)							
2.a.	Mice	822						145		967
2.b.	Rats									0
2.c.	Guinea-Pigs									0
2.d.	Hamsters									0
2.e.	Other Rodents									0
2.f.	Rabbits									0
2.g.	Cats									0
2.h.	Dogs									0
2.i.	Ferrets									0
2.j.	Other Carnivores									0
2.k.	Horses, donkeys and cross breds									0
2.1.	Pigs									0
2.m.	Goats									0
2.n.	Sheep									0
2.0.	Cattle									0
2.p.	Prosimians									0
2.q.	New World Monkeys									0
2.r.	Old World Monkeys									0
2.s.	Apes									0
2.t.	Other Mammals									0
2.u.	Quail									0
2.v.	Other birds									0
2.w.	Reptiles									0
2.x.	Amphibians									0
2.y.	Fish	000	_	_	_	_	_	,		0
2.z.	TOTAL	822	0	0	0	0	0	145	0	967

TABLE 4: NUMBER OF ANIMALS USED IN EXPERIMENTS FOR STUDIES ON HUMAN AND ANIMAL DISEASES

Main categories versus species

	4.1	4.2	4.3	4.4	4.5	4.6	4.7
	Species	Human cardiovascular	Human nervous and	Human cancer (excluding	Other human diseases	Studies specific to animal	Total
		diseases	mental disorders	evaluations of carcinogenic		diseases	
				hazards or risks)			
4.a.	Mice		792		175		967
4.b.	Rats						0
4.c.	Guinea-Pigs						0
4.d.	Hamsters						0
4.e.	Other Rodents						0
4.f.	Rabbits						0
4.g.	Cats						0
4.h.	Dogs						0
4.i.	Ferrets						0
4.j.	Other Carnivores						0
4.k.	Horses, donkeys and cross breds						0
4.1.	Pigs						0
4.m.	Goats						0
4.n.	Sheep						0
4.o.	Cattle						0
4.p.	Prosimians						0
4.q.	New World Monkeys						0
4.r.	Old World Monkeys						0
4.s.	Apes						0
4.t.	Other Mammals						0
4.u.	Quail						0
4.v.	Other birds						0
4.w.	Reptiles						0
4.x.	Amphibians						0
4.y.	Fish						0
4.z.	TOTAL	0	792	0	175	0	967

CZECH REPUBLIC

Statistical data submitted

The statistical data have been submitted by the "Central Commission for Animal Welfare (Ústřední komise pro ochranu zvířat)".

Comments of the Czech authorities

National comments for the preparation of the 5th Statistical report on the use of experimental animals - Czech Republic

Protection of animals and animal welfare in the Czech Republic is the responsibility of the Ministry of Agriculture, which provides the organisation background necessary for the activities performed by the Central Commission for Animal Welfare (Ústřední komise pro ochranu zvířat). The animal welfare activities are implemented pursuant to Act No. 246/1992 Coll., on the protection of animals against cruelty, as amended. The supervision over these matters has been the responsibility of the Regional Veterinary Administrations' inspectors in 13 regions of the Czech Republic and the Municipal Veterinary Administration in Prague.

There were 93 inspections conducted in laboratory animal breeding establishments involving 120 067 animals, corrective measures were imposed in 3 cases and administrative procedure was initiated twice

In 2005 a total of 330 933 animals were used for experimental and other scientific purposes in the CR. It shall be pointed out that 36.99 % of it is represented by ringed birds (122 422 birds) since pursuant to the relevant Czech legislation even bird ringing is an experiment.

Of the remaining 208 511 animals used for experimental and scientific purposes only 0.01 % were cats (29 cats), 0.13 % dogs (264 dogs), 0.02 % monkeys (51 monkeys), while no apes were used. Rodents and rabbits (62.16 %, i.e. 129 615 animals) and fish (33.29 %, i.e. 69 418 fish) represent the prevailing majority of animals used.

In the last couple of years the number of experimental animals used in the CR was approximately the same (approximately 220 000 animals excluding ringed birds). Fluctuations in numbers, if any, are caused by experiments using fish and poultry because these experiments are usually conducted on a large group of animals (a flock in houses or stock in water reservoirs).

The use of alternative methods to experiments on animals has been pushed through in the CR. Persons who manage, control and conduct experiments on animals are obliged to seek in the registers of validated alternative methods such methods which are applicable to their experiment. In the experimental project the applicant shall declare in writing that no validated alternative method can be applied for the given purpose.

The training courses for persons who manage, control and conduct experiments on animals comprise also teaching of alternative methods to experiments on animals.

Doc. MVDr. Richard S O V J Á K, CSc.

Chairman

TABLE 1: NUMBER OF ANIMALS USED IN RELATION TO THEIR PLACE OF ORIGIN

Origin versus species

	1.1	1.2	1.3	1.4	1.5	1.6	1.7
	Species	Total	Animals coming from registered	Animals coming from	Animals coming from	Animals coming from	Re-used animals
			breeding or supplying	elsewhere in the EC	Member Countries of the	other origins	
			establishments within the reporting		Council of Europe which are		
			country		parties to the Convention ETS		
					123 (excluding EC Member		
					States)		
1.a.	Mice (Mus musculus)	82252	75473	4708	2071		
1.b.	Rats (Rattus norvegicus)	31703	29924	1087	240	452	
1.c.	Guinea-Pigs (Cavia porcellus)	4075	4075				
1.d.	Hamsters (Mesocricetus)	220	220				
1.e.	Other Rodents (other Rodentia)	5798					
1.f.	Rabbits (Oryctolagus cuniculus)	5567	5567				119
1.g.	Cats (Felis catus)	29	3			26	
1.h.	Dogs (Canis familiaris)	264	264				24
1.i.	Ferrets (Mustela putorius furo)	159	159				
1.j.	Other Carnivores (other Carnivora)	7					
1.k.	Horses, donkeys and cross breds (Equidae)	314					
1.l.	Pigs (Sus)	1392					
1.m.	Goats (Capra)	56					
1.n.	Sheep (Ovis)	720					
1.0.	Cattle (Bos)	711					
1.p.	Prosimians (Prosimia)	0					
1.q.	New World Monkeys (Ceboidea)	0					
1.r.	Old World Monkeys (Cercopithecoidea)	51	51				30
1.s.	Apes (Hominoidea)	0					
1.t.	Other Mammals (other Mammalia)	188					
1.u.	Quail (Coturnix coturnix)	30	30				
1.v.	Other birds (other Aves)	126211					
1.w.	Reptiles (Reptilia)	1475					
1.x.	Amphibians (Amphibia)	293					
1.y.	Fish (Pisces)	69418					
1.z.	TOTAL	330933					

Note 1: Column 1.5 concerns only those Member Countries of the Council of Europe which, at the beginning of the reporting period, are Parties to the Convention ETS 123. Thus an updated list of those countries has to be used when filling in this column.

Note 2: Only the white boxes need to be completed.

Note 3: The number of re-used animals in column 1.7 should be excluded from the total in the column 1.2

TABLE 2: NUMBER OF ANIMALS USED IN EXPERIMENTS FOR SELECTED PURPOSES

Purpose versus species

	2.1	2.2	2.3	2.4	2.5	2.6	2.7	2.8	2.9	2.10
	Species	Biologic	Research and	Production and	Production and	Toxicological	Diagnosis of	Education and	Other	Total
		al	development of	quality control of	quality control of	and other safety	disease	training		
		studies	products and	products and	products and	evaluations				
		of a	devices for human	devices for	devices for	(including				
		fundame	medicine and	human medicine	veterinary	safety				
		ntal	dentistry and for	and dentistry	medicine	evaluation of				
		nature	veterinary			products and				
			medicine			devices for				
			(excluding toxicological and			human medicine and				
			other safety			dentistry and				
			evaluations			for veterinary				
			counted in column			medicine)				
			2.6)			medicine)				
2.a.	Mice	33319	4698	8962	14401	2673	9320	3338	5541	82252
2.b.	Rats	25532	2462	146	920	911	77	1655		31703
2.c.	Guinea-Pigs	433	4	1575	1048	527	457	31		4075
2.d.	Hamsters	115		55	40		10			220
2.e.	Other Rodents	5449			187			162		5798
2.f.	Rabbits	352	16	1351	2962	448	344	83	11	5567
2.g.	Cats	3			26					29
2.h.	Dogs	4		10	100	145	5			264
2.i.	Ferrets		126	7			6	20		159
2.j.	Other Carnivores	7								7
2.k.	Horses, donkeys and cross breds				208			100	6	314
2.1.	Pigs	502			569		85	236		1392
2.m.	Goats	56								56
2.n.	Sheep	83			51			19	567	720
2.o.	Cattle	152	241		40		12	84	182	711
2.p.	Prosimians									0
2.q.	New World Monkeys									0
2.r.	Old World Monkeys					51				51
2.s.	Apes									0
2.t.	Other Mammals	188								188
2.u.	Quail					30				30
2.v.	Other birds	122422		42	2556		6	585	600	126211
2.w.	Reptiles	755		·				720		1475
2.x.	Amphibians	208						85		293
2.y.	Fish	26935			1422	26693	870	11866	1632	69418
2.z.	TOTAL	216515	7547	12148	24530	31478	11192	18984	8539	330933

TABLE 3: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS

Products versus species

		•					-	.			
	3.1	3.2	3.3	3.4	3.5	3.6	3.7	3.8	3.9	3.10	3.11
	Species	Products/	Products/	Products/	Products/	Products/	Products/	Products/	Potential or	Other toxico-	Total
		substances or	substances	substances	substances	substances	substances	substances	actual contami-	logical or	
		devices for	used or	used or	used or	used or	used or	used or	nents in the	safety	
		human	intended to	intended to	intended to	intended to	intended to be	intended to be	general envi-	evaluations	
		medicine and	be used	be used	be used	be used	used mainly	used mainly	ronment which		
		dentistry and	mainly in	mainly in	mainly in	mainly as	as additives in	as additives in	do not appear in		
		for veterinary	agriculture	industry	the	cosmetics	food for	food for	other columns		
		medicine			household	or toiletries	human	animal			
2) C	2000					consumption	consumption	105		207
3.a.	Mice	2300		68				600	405		337
3.b.	Rats	663	00	248				150	200		126
3.c.	Guinea-Pigs	30	26	471							52
3.d.	Hamsters										
3.e.	Other Rodents										
3.f.	Rabbits	245	4	174					25		44
3.g.	Cats										
3.h.	Dogs	145									14
3.i.	Ferrets										
3.j.	Other Carnivores										
3.k.	Horses, donkeys and cross breds										
3.1.	Pigs										
3.m.	Goats										
3.n.	Sheep										
3.0.	Cattle										
3.p.	Prosimians										
3.q.	New World Monkeys										
3.r.	Old World Monkeys	51									5
3.s.	Apes										
3.t.	Other Mammals										
3.u.	Quail								25		2
3.v.	Other birds								-		
3.w.	Reptiles										
3.x.	Amphibians										
3.y.	Fish	1468	90	2676					19523	1891	2564
3.z.	TOTAL	4902	120	3637	0	0	0	750	20178	1891	3147
		.502	0	5551				. 00	_0110	.001	3111

TABLE 4: NUMBER OF ANIMALS USED IN EXPERIMENTS FOR STUDIES ON HUMAN AND ANIMAL DISEASES

Main categories versus species

	4.1	4.2	4.3	4.4	4.5	4.6	4.7
	Species	Human cardiovascular	Human nervous and	Human cancer (excluding	Other human diseases	Studies specific to animal	Total
		diseases	mental disorders	evaluations of carcinogenic		diseases	
				hazards or risks)			
4.a.	Mice	1473	1230	9036	15146	4672	31557
4.b.	Rats	5697	2896	694	6104	136	15527
4.c.	Guinea-Pigs	10			13	6	29
4.d.	Hamsters				10	20	30
4.e.	Other Rodents					361	361
4.f.	Rabbits	167		3	161	72	403
4.g.	Cats	3					3
4.h.	Dogs	2					2
4.i.	Ferrets	126			6		132
4.j.	Other Carnivores						0
4.k.	Horses, donkeys and cross breds						0
4.1.	Pigs	31		30	188	40	289
4.m.	Goats					56	56
4.n.	Sheep	29				28	57
4.o.	Cattle					17	17
4.p.	Prosimians						0
4.q.	New World Monkeys						0
4.r.	Old World Monkeys						0
4.s.	Apes						0
4.t.	Other Mammals						0
4.u.	Quail				5		5
4.v.	Other birds				111	1093	1204
4.w.	Reptiles						0
4.x.	Amphibians						0
4.y.	Fish					1430	1430
4.z.	TOTAL	7538	4126	9763	21744	7931	51102

TABLE 5: NUMBER OF ANIMALS USED IN PRODUCTION AND QUALITY CONTROL OF PRODUCTS AND DEVICES FOR HUMAN MEDICINE AND DENTISTRY AND FOR VETERINARY MEDICINE

Regulatory requirements versus species

				, requirements versus	· · · <u>I</u> · · · · · · ·			
	5.1 Species	5.2 National legislation	5.3 EC legislation	5.4 Member Country of Council	5.5 Other legislation	5.6 Any combination of	5.7 No regulatory	5.8 Total
	Species	specific to a single EC	including European	of Europe (but not EC)	Other registation	5.2/ 5.3/ 5.4/ 5.5	requirements	Total
		Member State	Pharmacopoeia	legislation		3.2/ 3.3/ 3.4/ 3.3	requirements	
		1)	(requirements)	2)				
5.a.	Mice	4422	17623	2)			1368	23413
5.b.	Rats	211	880		8		117	1216
5.c.	Guinea-Pigs	3	2620		0		117	2623
5.d.	Hamsters	3	95					95
			90			187		187
5.e.	Other Rodents	400	0.400		4.4	187	000	
5.f.	Rabbits	483	3433		11		386	4313
5.g.	Cats		26					26
5.h.	Dogs		110					110
5.i.	Ferrets		7					7
5.j.	Other Carnivores							0
5.k.	Horses, donkeys and cross breds	205	3					208
5.1.	Pigs		556				13	569
5.m.	Goats							0
5.n.	Sheep		51					51
5.0.	Cattle		40					40
5.p.	Prosimians							0
5.q.	New World Monkeys							0
5.r.	Old World Monkeys							0
5.s.	Apes							0
5.t.	Other Mammals							0
5.u.	Quail							0
5.v.	Other birds		2543				55	2598
5.w.	Reptiles							0
5.x.	Amphibians							0
5.y.	Fish	1222						1222
5.z.	TOTAL	6546	27987	0	19	187	1939	36678
		1						

Examples:

Footnotes:

5.2 – France is testing due to a UK (or FR) specific requirement

5.3 - UK is testing according to EC legislation

5.4 – Spain is testing due to a Hungarian requirement

5.5 – Sweden is testing due to a US specific requirement

5.6 - Germany is testing due to a Czech requirement (also an EC

requirement)

Note: columns 5.2 - 5.5 refer to the legislation imposing that the test be carried out and

not to the body which has issued the actual test method, guideline or protocol.

a test required by French legislation and carried out in Belgium according to an

ISO protocol must be coded as a national (FR) legislative requirement and be

Entered into column 5.2 in the tables submitted by Belgium.

- 1) EC Member States: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden, United Kingdom
- Member Countries of Council of Europe (non-EC): Albania, Andorra, Bulgaria, Croatia, Cyprus, Czech Rep., Estonia, Hungary, Iceland, Latvia, Liechtenstein, Lithuania, Malta, Moldova, Norway, Poland, Romania, Russia, San Marino, Slovakia, Slovenia, Switzerland, 'the former Yugoslav Rep. of Macedonia', Turkey, Ukraine

Example:

TABLE 6: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS

Regulatory requirements versus species

	6.1	6.2	6.3	6.4	6.5	6.6	6.7	6.8
	Species	National legislation	EC legislation	Member Country of Council	Other legislation	Any combination of	No regulatory	Total
	•	specific to a single EC	including European	of Europe (but not EC)	·	6.2/ 6.3/ 6.4/ 6.5	requirements	
		Member State	Pharmacopoeia	legislation				
		1)	(requirements)	2)				
6.a.	Mice	278	2170				225	2673
6.b.	Rats	224	663	24				911
6.c.	Guinea-Pigs	351	106	70				527
6.d.	Hamsters							0
6.e.	Other Rodents							0
6.f.	Rabbits	182	257	9				448
6.g.	Cats							0
6.h.	Dogs		145					145
6.i.	Ferrets							0
6.j.	Other Carnivores							0
6.k.	Horses, donkeys and cross breds							0
6.1.	Pigs							0
6.m.	Goats							0
6.n.	Sheep							0
6.0.	Cattle							0
6.p.	Prosimians							0
6.q.	New World Monkeys							0
6.r.	Old World Monkeys		51					51
6.s.	Apes							0
6.t.	Other Mammals							0
6.u.	Quail						25	25
6.v.	Other birds							0
6.w.	Reptiles							0
6.x.	Amphibians		_					0
6.y.	Fish	6476	15055	312			4855	26698
6.z.	TOTAL	7511	18447	415	0	0	5105	31478

Examples:

6.2 – France is testing due to a UK (or FR) specific requirement

6.3 - UK is testing according to EC legislation

6.4 – Spain is testing due to a Hungarian requirement

6.5 – Sweden is testing due to a US specific requirement

6.6 - Germany is testing due to a Czech requirement (also an EC requirement)

Note: columns 6.2 - 6.5 refer to the legislation imposing that the test be carried out and

not to the body which has issued the actual test method, guideline or protocol.

a test required by French legislation and carried out in Belgium according to an

ISO protocol must be coded as a national (FR) legislative requirement and be

entered into column 6.2 in the tables submitted by Belgium.

Footnotes:

EC Member States: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden, United Kingdom

Member Countries of Council of Europe (non-EC): Albania, Andorra, Bulgaria, Croatia, Cyprus, Czech Rep., Estonia, Hungary, Iceland, Latvia, Liechtenstein, Lithuania, Malta, Moldova, Norway, Poland, Romania, Russia, San Marino, Slovakia, Slovenia, Switzerland, 'the former Yugoslav Rep. of Macedonia', Turkey, Ukraine

Example:

TABLE 7: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS

Types of tests versus species

	7.1 Species Acute and sub-acute toxicity testing method (including limit test)		testing methods	7.3 Skin	7.4 Skin	7.5 Eye	7.6 Sub-	7.7 Carcino-	7.8 Develop-	7.9 Muta-	7.10 Repro-	7.11 Toxicity	7.12 Other	7.13 Total	
	(including limit test)			irritation	sensitisatio n	irritation	chronic and chronic toxicity	genicity	mental toxicity	genicit y	ductive toxicity	to aquatic vertebra- tes not included in other			
		7.2.1. LD50, LC50	7.2.2 Other lethal methods	7.2.3 Non lethal clinical signs methods									columns		
7.a.	Mice	1055				68		1115		120		90		225	2673
7.b.	Rats	298						613							911
7.c.	Guinea-Pigs				40	487									527
7.d.	Hamsters														0
7.e.	Other Rodents														0
7.f.	Rabbits				259		164				25				448
7.g.	Cats														0
7.h.	Dogs							145							145
7.i.	Ferrets														0
7.j.	Other Carnivores														0
7.k.	Horses, donkeys and cross breds														0
7.1.	Pigs														0
7.m.	Goats														0
7.n.	Sheep														0
7.o.	Cattle														0
7.p.	Prosimians														0
7.q.	New World Monkeys														0
7.r.	Old World Monkeys							51							51
7.s.	Apes														0
7.t.	Other Mammals														0
7.u.	Quail			25					_						25
7.v.	Other birds														0
7.w.	Reptiles														0
7.x.	Amphibians														0
7.y.	Fish	22501						155				1600	2442		26698
7.z.	TOTAL	23854	0	25	299	555	164	2079	0	120	25	1690	2442	225	31478

TABLE 8: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS

Types of tests versus products

	8.1 Products		8.2 nd sub-acute toxi ods (including li		8.3 Skin irritation	8.4 Skin sensitisatio n	8.5 Eye irritation	8.6 Sub- chronic and chronic toxicity	8.7 Carcino genicity	8.8 Develop- mental toxicity	8.9 Muta- genicit y	8.10 Reproductive toxicity	8.11 Toxicity to aquatic vertebra- tes not included in other columns	8.12 Other	8.13 Total
		8.2.1. LD50, LC50	8.2.2 Other lethal methods	8.2.3 Non lethal clinical signs methods											
8.a.	Products/substances or devices for human medicine and dentistry and for veterinary medicine	1213			145	30	100	1924							3412
8.b.	Products/substances used or intended to be used mainly in agriculture	90			12	18									120
8.c.	Products/substances used or intended to be used mainly in industry	1450			142	507	64	100					1374		3637
8.d.	Products/substances used or intended to be used mainly in the household														0
8.e.	Products/substances used or intended to be used mainly as cosmetics or toiletries														0
8.f.	Products/substances used or intended to be used mainly as additives in food for human consumption														0
8.g.	Products/substances used or intended to be used mainly as additives in food for animal consumption														0
8.h.	Potential or actual contaminants in the general environment which do not appear in other columns	19510		25						120	25	90	1068		20838
8.i.	Other toxicological or safety evaluations	591											2655	225	3471
8.j.	TOTAL	22854	0	25	299	555	164	2024	0	120	25	90	5097	225	31478

DENMARK

Statistical data submitted

The statistical data have been submitted by the "Dyreforsøgstilsynet" (Animal Experiments Inspectorate).

Comments of Danish authorities

None

TABLE 1: NUMBER OF ANIMALS USED IN RELATION TO THEIR PLACE OF ORIGIN

Origin versus species

1.1	1.2	1.3	1.4	1.5	1.6	1.7
Species	Total	Animals coming from registered	Animals coming from	Animals coming from	Animals coming from	Re-used animals
		breeding or supplying	elsewhere in the EC	Member Countries of the	other origins	
		establishments within the reporting		Council of Europe which are		
		country		parties to the Convention ETS		
				123 (excluding EC Member		
1 W ()(1)	000075	400000	00570	States)	0500	4.45
1.a. Mice (Mus musculus)	208375	109300	96573	0	2502	145
1.b. Rats (Rattus norvegicus)	85664	45960	37649	725	1330	71
1.c. Guinea-Pigs (Cavia porcellus)	5046	1204	3838	0	4	2
1.d. Hamsters (Mesocricetus)	402	402	0	0	0	0
1.e. Other Rodents (other <i>Rodentia</i>)	6381	0	0	0	0	0
1.f. Rabbits (Oryctolagus cuniculus)	5805	4288	1359	18	140	739
1.g. Cats (Felis catus)	16	4	0	4	8	0
1.h. Dogs (Canis familiaris)	566	10	514	0	42	84
1.i. Ferrets (Mustela putorius furo)	19	0	0	0	19	0
1.j. Other Carnivores (other <i>Carnivora</i>)	242	0	0	0	0	0
1.k. Horses, donkeys and cross breds (Equidae)	62	0	0	0	0	0
1.1. Pigs (<i>Sus</i>)	7697	0	0	0	0	0_
1.m. Goats (Capra)	199	0	0	0	0	0
1.n. Sheep (Ovis)	156	0	0	0	0	0
1.o. Cattle (Bos)	489	0	0	0	0	0
1.p. Prosimians (<i>Prosimia</i>)	0	0	0	0	0	0
1.q. New World Monkeys (Ceboidea)	0	0	0	0	0	0
1.r. Old World Monkeys (Cercopithecoidea)	0	0	0	0	0	0
1.s. Apes (Hominoidea)	0	0	0	0	0	0
1.t. Other Mammals (other <i>Mammalia</i>)	185	0	0	0	0	0
1.u. Quail (Coturnix coturnix)	0	0	0	0	0	0
1.v. Other birds (other <i>Aves</i>)	7784	0	0	0	0	0
1.w. Reptiles (Reptilia)	54	0	0	0	0	0
1.x. Amphibians (Amphibia)	840	0	0	0	0	0
1.y. Fish (Pisces)	35958	0	0	0	0	0
1.z. TOTAL	365940	0	0	0	0	0

Note 1: Column 1.5 concerns only those Member Countries of the Council of Europe which, at the beginning of the reporting period, are Parties to the Convention ETS 123. Thus an updated list of those countries has to be used when filling in this column.

Note 2: Only the white boxes need to be completed.

Note 3: The number of re-used animals in column 1.7 should be excluded from the total in the column 1.2

TABLE 2: NUMBER OF ANIMALS USED IN EXPERIMENTS FOR SELECTED PURPOSES

Purpose versus species

	2.1	2.2	2.3	2.4	2.5	2.6	2.7	2.8	2.9	2.10
	Species	Biological	Research and	Production and	Production and	Toxicological	Diagnosis of	Education and	Other	Total
		studies of a	development of	quality control of	quality control of	and other safety	disease	training		
		fundamenta	products and	products and	products and	evaluations				
		l nature	devices for human	devices for	devices for	(including				
			medicine and	human medicine	veterinary	safety				
			dentistry and for	and dentistry	medicine	evaluation of				
			veterinary			products and				
			medicine			devices for				
			(excluding toxicological and			human medicine and				
			other safety			dentistry and				
			evaluations			for veterinary				
			counted in column			medicine)				
			2.6)			medicine)				
2.a.	Mice	50339	128153	13842	165	3742	2524	1441	8169	208375
2.b.	Rats	18795	54087	860	0	8786	703	1984	449	85664
2.c.	Guinea-Pigs	393	850	1434	0	2303	66	0	0	5046
2.d.	Hamsters	338	0	0	0	64	0	0	0	402
2.e.	Other Rodents	0	6343	0	0	0	38	0	0	6381
2.f.	Rabbits	247	700	882	82	556	3232	104	2	5805
2.g.	Cats	12	0	0	0	0	0	4	0	16
2.h.	Dogs	46	109	0	0	407	0	4	0	566
2.i.	Ferrets	19	0	0	0	0	0	0	0	19
2.j.	Other Carnivores	242	0	0	0	0	0	0	0	242
2.k.	Horses, donkeys and cross	39	0	12	0	0	0	11	0	62
	breds									
2.1.	Pigs	3992	1807	20	29	581	483	350	435	7697
2.m.	Goats	26	3	0	0	0	163	1	6	199
2.n.	Sheep	125	27	4	0	0	0	0	0	156
2.o.	Cattle	444	30	0	2	0	0	13	0	489
2.p.	Prosimians	0	0	0	0	0	0	0	0	0
2.q.	New World Monkeys	0	0	0	0	0	0	0	0	0
2.r.	Old World Monkeys	0	0	0	0	0	0	0	0	0
2.s.	Apes	0	0	0	0	0	0	0	0	0
2.t.	Other Mammals	137	48	0	0	0	0	0	0	185
2.u.	Quail	0	0	0	0	0	0	0	0	0
2.v.	Other birds	2695	0	2	0	0	5087	0	0	7784
2.w.	Reptiles	54	0	0	0	0	0	0	0	54
2.x.	Amphibians	597	93	0	0	0	0	150	0	840
2.y.	Fish	10284	23710	0	0	1480	0	84	400	35958
2.z.	TOTAL	88824	215960	17056	278	17919	12296	4146	9461	365940

TABLE 3: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS

Products versus species

	3.1	3.2	3.3	3.4	3.5	3.6	3.7	3.8	3.9	3.10	3.11
	Species	Products/	Products/	Products/	Products/	Products/	Products/	Products/	Potential or	Other toxico-	Total
		substances or	substances	substances	substances	substances	substances	substances	actual contami-	logical or	
		devices for	used or	used or	used or	used or	used or	used or	nents in the	safety	
		human	intended to	intended to	intended to	intended to	intended to be	intended to be	general envi-	evaluations	
		medicine and	be used	be used	be used	be used	used mainly	used mainly	ronment which		
		dentistry and	mainly in	mainly in	mainly in	mainly as	as additives in	as additives in	do not appear in		
		for veterinary	agriculture	industry	the	cosmetics	food for	food for	other columns		
		medicine			household	or toiletries	human	animal			
							consumption	consumption			
3.a.	Mice	2733	0	556	51	0	0	0	25	377	3742
3.b.	Rats	5453	2138	355	134	0	33	0	561	112	8786
3.c.	Guinea-Pigs	2102	0	45	0	0	0	0	156	0	2303
3.d.	Hamsters	64	0	0	0	0	0	0	0	0	64
3.e.	Other Rodents	0	0	0	0	0	0	0	0	0	0
3.f.	Rabbits	407	0	9	0	0	135	0	0	5	556
3.g.	Cats	0	0	0	0	0	0	0	0	0	0
3.h.	Dogs	407	0	0	0	0	0	0	0	0	407
3.i.	Ferrets	0	0	0	0	0	0	0	0	0	0
3.j.	Other Carnivores	0	0	0	0	0	0	0	0	0	0
3.k.	Horses, donkeys and cross breds	0	0	0	0	0	0	0	0	0	0
3.1.	Pigs	581	0	0	0	0	0	0	0	0	581
3.m.	Goats	0	0	0	0	0	0	0	0	0	0
3.n.	Sheep	0	0	0	0	0	0	0	0	0	0
3.0.	Cattle	0	0	0	0	0	0	0	0	0	0
3.p.	Prosimians	0	0	0	0	0	0	0	0	0	0
3.q.	New World Monkeys	0	0	0	0	0	0	0	0	0	0
3.r.	Old World Monkeys	0	0	0	0	0	0	0	0	0	0
3.s.	Apes	0	0	0	0	0	0	0	0	0	0
3.t.	Other Mammals	0	0	0	0	0	0	0	0	0	0
3.u.	Quail	0	0	0	0	0	0	0	0	0	0
3.v.	Other birds	0	0	0	0	0	0	0	0	0	0
3.w.	Reptiles	0	0	0	0	0	0	0	0	0	0
3.x.	Amphibians	0	0	0	0	0	0	0	0	0	0
3.y.	Fish	0	0	1080	0	0	0	0	400	0	1480
3.z.	TOTAL	11747	2138	2045	185	0	168	0	1142	494	17919

TABLE 4: NUMBER OF ANIMALS USED IN EXPERIMENTS FOR STUDIES ON HUMAN AND ANIMAL DISEASES

Main categories versus species

	4.1	4.2	4.3	4.4	4.5	4.6	4.7
	Species	Human cardiovascular	Human nervous and	Human cancer (excluding	Other human diseases	Studies specific to animal	Total
		diseases	mental disorders	evaluations of carcinogenic		diseases	
				hazards or risks)			
4.a.	Mice	1902	92293	20255	30999	716	146165
4.b.	Rats	3072	35360	332	27760	96	66620
4.c.	Guinea-Pigs	65	629	0	281	24	999
4.d.	Hamsters	171	0	0	0	0	171
4.e.	Other Rodents	0	5923	0	420	0	6343
4.f.	Rabbits	142	8	0	740	2	892
4.g.	Cats	0	12	0	0	0	12
4.h.	Dogs	0	17	0	92	42	151
4.i.	Ferrets	0	19	0	0	0	19
4.j.	Other Carnivores	0	0	0	0	102	102
4.k.	Horses, donkeys and cross breds	0	0	0	0	26	26
4.1.	Pigs	254	172	0	1616	665	2707
4.m.	Goats	0	0	0	29	0	29
4.n.	Sheep	0	0	0	50	0	50
4.0.	Cattle	0	0	0	0	10	10
4.p.	Prosimians	0	0	0	0	0	0
4.q.	New World Monkeys	0	0	0	0	0	0
4.r.	Old World Monkeys	0	0	0	0	0	0
4.s.	Apes	0	0	0	0	0	0
4.t.	Other Mammals	0	0	0	0	0	0
4.u.	Quail	0	0	0	0	0	0
4.v.	Other birds	0	0	0	0	3714	3714
4.w.	Reptiles	0	0	0	0	0	0
4.x.	Amphibians	0	127	0	0	0	127
4.y.	Fish	0	0	0	0	2800	2800
4.z.	TOTAL	5606	134560	20587	61987	8197	230937

TABLE 5: NUMBER OF ANIMALS USED IN PRODUCTION AND QUALITY CONTROL OF PRODUCTS AND DEVICES FOR HUMAN MEDICINE AND DENTISTRY AND FOR VETERINARY MEDICINE

Regulatory requirements versus species

	5.1	5.2	5.3	5.4	5.5	5.6	5.7	5.8
	Species	National legislation	EC legislation	Member Country of Council	Other legislation	Any combination of	No regulatory	Total
		specific to a single EC	including European	of Europe (but not EC)		5.2/ 5.3/ 5.4/ 5.5	requirements	
		Member State	Pharmacopoeia	legislation				
		1)	(requirements)	2)				
5.a.	Mice	86	517	0	0	12882	522	14007
5.b.	Rats	96	0	0	0	764	0	860
5.c.	Guinea-Pigs	0	0	0	0	1332	102	1434
5.d.	Hamsters	0	0	0	0	0	0	0
5.e.	Other Rodents	0	0	0	0	0	0	0
5.f.	Rabbits	7	0	0	30	397	530	964
5.g.	Cats	0	0	0	0	0	0	0
5.h.	Dogs	0	0	0	0	0	0	0
5.i.	Ferrets	0	0	0	0	0	0	0
5.j.	Other Carnivores	0	0	0	0	0	0	0
5.k.	Horses, donkeys and cross breds	0	0	0	0	0	12	12
5.1.	Pigs	25	0	0	0	24	0	49
5.m.	Goats	0	0	0	0	0	0	0
5.n.	Sheep	0	0	0	0	0	4	4
5.0.	Cattle	0	0	0	0	2	0	2
5.p.	Prosimians	0	0	0	0	0	0	0
5.q.	New World Monkeys	0	0	0	0	0	0	0
5.r.	Old World Monkeys	0	0	0	0	0	0	0
5.s.	Apes	0	0	0	0	0	0	0
5.t.	Other Mammals	0	0	0	0	0	0	0
5.u.	Quail	0	0	0	0	0	0	0
5.v.	Other birds	0	0	0	2	0	0	2
5.w.	Reptiles	0	0	0	0	0	0	0
5.x.	Amphibians	0	0	0	0	0	0	0
5.y.	Fish	0	0	0	0	0	0	0
5.z.	TOTAL	214	517	0	32	15401	1170	17334
Exar	nples: 5.2 – France is testing due	to a UK (or FR) specific	requirement	Note: columns 5.2 -	5.5 refer to the legisla	ation imposing that the test	be carried out and	

5.3 - UK is testing according to EC legislation

5.4 – Spain is testing due to a Hungarian requirement

5.5 – Sweden is testing due to a US specific requirement

5.6 - Germany is testing due to a Czech requirement (also an EC

requirement)

Example:

not to the body which has issued the actual test method, guideline or protocol.

a test required by French legislation and carried out in Belgium according to an

ISO protocol must be coded as a national (FR) legislative requirement and be

entered into column 5.2 in the tables submitted by Belgium.

Footnotes:

EC Member States: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden, United Kingdom

Member Countries of Council of Europe (non-EC): Albania, Andorra, Bulgaria, Croatia, Cyprus, Czech Rep., Estonia, Hungary, Iceland, Latvia, Liechtenstein, Lithuania, Malta, Moldova, Norway, Poland, Romania, Russia, San Marino, Slovakia, Slovenia, Switzerland, 'the former Yugoslav Rep. of Macedonia', Turkey, Ukraine

NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS TABLE 6:

Regulatory requirements versus species

	6.1 Species	6.2 National legislation specific to a single EC Member State 1)	6.3 EC legislation including European Pharmacopoeia (requirements)	6.4 Member Country of Council of Europe (but not EC) legislation 2)	6.5 Other legislation	6.6 Any combination of 6.2/ 6.3/ 6.4/ 6.5	6.7 No regulatory requirements	6.8 Total
6.a.	Mice	223	0	0	0	2190	1329	3742
6.b.	Rats	0	0	0	0	5850	2936	8786
6.c.	Guinea-Pigs	0	0	0	0	2112	191	2303
6.d.	Hamsters	0	0	0	0	64	0	64
6.e.	Other Rodents	0	0	0	0	0	0	0
6.f.	Rabbits	0	0	0	0	416	140	556
6.g.	Cats	0	0	0	0	0	0	0
6.h.	Dogs	0	0	0	0	407	0	407
6.i.	Ferrets	0	0	0	0	0	0	0
6.j.	Other Carnivores	0	0	0	0	0	0	0
6.k.	Horses, donkeys and cross breds	0	0	0	0	0	0	0
6.l.	Pigs	0	0	0	0	581	0	581
6.m.	Goats	0	0	0	0	0	0	0
6.n.	Sheep	0	0	0	0	0	0	0
6.0.	Cattle	0	0	0	0	0	0	0
6.p.	Prosimians	0	0	0	0	0	0	0
6.q.	New World Monkeys	0	0	0	0	0	0	0
6.r.	Old World Monkeys	0	0	0	0	0	0	0
6.s.	Apes	0	0	0	0	0	0	0
6.t.	Other Mammals	0	0	0	0	0	0	0
6.u.	Quail	0	0	0	0	0	0	0
6.v.	Other birds	0	0	0	0	0	0	0
6.w.	Reptiles	0	0	0	0	0	0	0
6.x.	Amphibians	0	0	0	0	0	0	0
6.y.	Fish	0	0	0	1080	0	400	1480
6.z.	TOTAL	223	0	0	1080	11620	4996	17919

Examples:

6.2 – France is testing due to a UK (or FR) specific requirement

6.3 - UK is testing according to EC legislation

6.4 – Spain is testing due to a Hungarian requirement

6.5 – Sweden is testing due to a US specific requirement

6.6 - Germany is testing due to a Czech requirement (also an EC requirement)

Note:

columns 6.2 - 6.5 refer to the legislation imposing that the test be carried out and

not to the body which has issued the actual test method, guideline or protocol.

Example: a test required by French legislation and carried out in Belgium according to an

ISO protocol must be coded as a national (FR) legislative requirement and be

entered into column 6.2 in the tables submitted by Belgium.

Footnotes:

EC Member States: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden, United Kingdom

Member Countries of Council of Europe (non-EC): Albania, Andorra, Bulgaria, Croatia, Cyprus, Czech Rep., Estonia, Hungary, Iceland, Latvia, Liechtenstein, Lithuania, Malta, Moldova, Norway, Poland, Romania, Russia, San Marino, Slovakia, Slovenia, Switzerland, 'the former Yugoslav Rep. of Macedonia', Turkey, Ukraine

TABLE 7: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS

Types of tests versus species

	7.1 Species		7.2 ab-acute toxicity t		7.3 Skin	7.4 Skin	7.5 Eye	7.6 Sub-	7.7 Carcino-	7.8 Develop-	7.9 Muta-	7.10 Repro-	7.11 Toxicity	7.12 Other	7.13 Total
		((including limit to	est)	irritation	sensitisatio n	irritation	chronic and chronic toxicity	genicity	mental toxicity	genicit y	ductive toxicity	to aquatic vertebra- tes not		
								toxicity					included in other		
													columns		
		7.2.1.	7.2.2	7.2.3											
		LD50, LC50	Other lethal methods	Non lethal clinical signs											
		LC30	methods	methods											
7.a.	Mice	0	0	2363	0	30	0	216	0	0	325	14	0	794	3742
7.b.	Rats	0	0	1244	0	0	0	4585	3	116	0	2612	0	226	8786
7.c.	Guinea-Pigs	0	0	1177	0	801	0	169	0	0	0	0	0	156	2303
7.d.	Hamsters	0	0	28	0	0	0	36	0	0	0	0	0	0	64
7.e.	Other Rodents	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.f.	Rabbits	0	0	0	53	0	5	294	0	0	0	0	0	204	556
7.g.	Cats	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.h.	Dogs	0	0	20	0	0	0	381	0	0	0	0	0	6	407
7.i.	Ferrets	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.j.	Other Carnivores	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.k.	Horses, donkeys and cross breds	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.1.	Pigs	0	0	0	8	0	0	473	0	0	0	100	0	0	581
7.m.	Goats	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.n.	Sheep	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.o.	Cattle	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.p.	Prosimians	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.q.	New World Monkeys	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.r.	Old World Monkeys	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.s.	Apes	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.t.	Other Mammals	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.u.	Quail	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.v.	Other birds	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.w.	Reptiles	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.x.	Amphibians	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.y.	Fish	1080	0	0	0	0	0	0	0	0	0	0	400	0	1480
7.z.	TOTAL	1080	0	4832	61	831	5	6154	3	116	325	2726	400	1386	17919

TABLE 8: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS

Types of tests versus products

	8.1		8.2		8.3	8.4	8.5	8.6	8.7	8.8	8.9	8.10	8.11	8.12	8.13
	Products	meth	nd sub-acute tox ods (including li	mit test)	Skin irritation	Skin sensitisatio n	Eye irritation	Sub- chronic and chronic toxicity	Carcino genicity	Develop- mental toxicity	Muta- genicit y	Reproductive toxicity	Toxicity to aquatic vertebra- tes not included in other columns	Other	Total
		8.2.1. LD50, LC50	8.2.2 Other lethal methods	8.2.3 Non lethal clinical signs methods											
8.a.	Products/substances or devices for human medicine and dentistry and for veterinary medicine	0	0	4654	43	786	5	5739	0	116	48	100	0	320	11811
8.b.	Products/substances used or intended to be used mainly in agriculture	0	0	0	8	0	0	0	0	0	0	2051	0	14	2073
8.c.	Products/substances used or intended to be used mainly in industry	1080	0	105	9	45	0	350	0	0	0	0	400	456	2445
8.d.	Products/substances used or intended to be used mainly in the household	0	0	0	0	0	0	8	3	0	51	0	0	123	185
8.e.	Products/substances used or intended to be used mainly as cosmetics or toiletries	0	0	0	0	0	0	0	0	0	0	0	0	0	0
8.f.	Products/substances used or intended to be used mainly as additives in food for human consumption	0	0	34	0	0	0	0	0	0	0	0	0	135	169
8.g.	Products/substances used or intended to be used mainly as additives in food for animal consumption	0	0	0	0	0	0	0	0	0	0	0	0	0	0
8.h.	Potential or actual contaminants in the general environment which do not appear in other columns	0	0	0	0	0	0	0	0	0	0	561	0	181	742
8.i.	Other toxicological or safety evaluations	0	0	8	0	0	0	88	0	0	226	14	0	158	494
8.j.	TOTAL	1080	0	4801	60	831	5	6185	3	116	325	2726	400	1387	17919

GERMANY

Statistical data submitted

The statistical data have been submitted by the "Bundesministerium für Verbraucherschutz, Ernährung und Landwirtschaft" (Federal Ministry for Consumer protection, Food and Agriculture).

Comments of German authorities

Further to the German Government's communications of 27 July 2006 regarding statistical information on the use of animals for experimental purposes, I now inform you of the following:

The German Government seeks to reduce animal experiments and to support the development of alternative methods (point 8.6 paragraph 3 of the 11 November 2005 coalition agreement). For example, the volume of assistance for the support priority "methods to replace animal experiments" has been increased from €3.4 million in 2005 to €4 million in 2006 - an increase of almost 18%. Furthermore, for many years the Federal Ministry of Food, Agriculture and Consumer Protection has been awarding a "research prize to support work on methods aimed at restricting and replacing animal experiments"; the prize carries an award of €15 000. In 2006 the 25th animal protection research prize will be awarded.

Based at the Federal Institute for Risk Assessment, the Central Office for recording and assessing methods to replace animal experiments was established in 1989 as the first institution of its kind in the world. Its task is to promote potentially successful approaches to developing and validating replacement and complementary methods. The Central Office's budget for doing so was almost doubled between 1990 (€204 200) and 2005 (€375 000). High priority is accorded to replacing animal experiments in official registration and authorisation procedures in which animal experiments are stipulated. The scientists at the Federal Institute for Risk Assessment also undertake successful research work themselves. For example, the Central Office is heavily involved in EU research projects, undertakes research projects as part of major joint projects and takes part in validation studies and collaborative tests within the EU. Furthermore, for many years a database on methods to replace animal experiments has been maintained at the Federal Institute for Risk Assessment; the database is available free of charge to scientists from the research world and industry at http://www.dimdi.de/static/en/db/dbinfo/dbkurz/zt00.htm.

In 2005 in Germany 1 822 424 animals were used for experiments and other scientific purposes. That represents an increase of 20 971 animals or 1.2% compared with the previous year.

As in previous years, rodents are the largest group at 1 573 074 animals or 86%. It is striking that up to 2005 their share continually increased from 75% in 2001. The number of dogs and cats has increased by 581 and 395 respectively compared with the

previous year. The number of farm animals used has remained constant at around 20 000 a year.

Apes have not been used. In the case of old-world monkeys, new-world monkeys and prosimians, there has been an increase of 338 animals compared with the previous year. That is the second highest figure since 2000. Apes were last reported in Germany in 1991.

The decline by 92 270 or 59% in the number of fish used is encouraging. In particular, there has been a reduction by 64 083 fish within basic research and by 15 463 fish in toxicological tests to identify environmental risks.

Within biological basic research there has been a reduction by 42 014 animals (5.5%) and within toxicological investigations and tests by 1 562 (1.0%).

No uniform trend is discernible in the case of animals used in the diagnosis of diseases; while their number rose by 158% to 39 013 in 2004 compared with the previous year, it fell again to 13 661 in 2005 and was therefore lower than in 2004.

With regard to products or equipment for medicine, dentistry or veterinary medicine, their research and development saw a marked increase by 13 869 animals and their manufacture or quality control by 101 535 animals.

Of those animals, 58% were used to research diseases in humans or animals.

For legally stipulated experiments for the manufacture or quality control of products for medicine, dentistry or veterinary medicine, or for toxicological safety tests, 24.9% of the animals were used.

On behalf of the ministry,

Dr Polten

TABLE 1: NUMBER OF ANIMALS USED IN RELATION TO THEIR PLACE OF ORIGIN

Origin versus species

	1.1	1.2	1.3	1.4	1.5	1.6	1.7
	Species	Total	Animals coming from registered	Animals coming from	Animals coming from	Animals coming from	Re-used animals
	•		breeding or supplying	elsewhere in the EC	Member Countries of the	other origins	
			establishments within the reporting		Council of Europe which are		
			country		parties to the Convention ETS		
					123 (excluding EC Member		
					States)		
1.a.	Mice (Mus musculus)	1 084 358	921 971	141 721	18 197	2 469	
1.b.	Rats (Rattus norvegicus)	435 417	339 626	90 339	3 516	1 936	
1.c.	Guinea-Pigs (Cavia porcellus)	37 761	37 372	389	0	0	
1.d.	Hamsters (Mesocricetus)	7 916	6 965	861	13	77	
1.e.	Other Rodents (other Rodentia)	7 622					
1.f.	Rabbits (Oryctolagus cuniculus)	103 329	101 939	1 354	4	32	6 532
1.g.	Cats (Felis catus)	1 023	569	316	0	138	262
1.h.	Dogs (Canis familiaris)	4 868	2 923	671	0	1 274	1 056
1.i.	Ferrets (Mustela putorius furo)	560	131	4	0	425	4
1.j.	Other Carnivores (other Carnivora)	235					
1.k.	Horses, donkeys and cross breds (Equidae)	755					
1.1.	Pigs (Sus)	13 166					
1.m.	Goats (Capra)	275					
1.n.	Sheep (Ovis)	3 517					
1.o.	Cattle (Bos)	2 909					
1.p.	Prosimians (<i>Prosimia</i>)	99	0	99	0	0	81
1.q.	New World Monkeys (Ceboidea)	408	347	61	0	0	67
1.r.	Old World Monkeys (Cercopithecoidea)	1 579	120	247	0	1 212	327
1.s.	Apes (Hominoidea)	0	0	0	0	0	0
1.t.	Other Mammals (other Mammalia)	115					
1.u.	Quail (Coturnix coturnix)	2 457	2 457	0	0	0	
1.v.	Other birds (other Aves)	39 150					
1.w.	Reptiles (Reptilia)	136					
1.x.	Amphibians (Amphibia)	10 432					
1.y.	Fish (Pisces)	64 337					
1.z.	TOTAL	1 822 424					

Note 1: Column 1.5 concerns only those Member Countries of the Council of Europe which, at the beginning of the reporting period, are Parties to the Convention ETS 123. Thus an updated list of those countries has to be used when filling in this column.

Note 2: Only the white boxes need to be completed.

Note 3: The number of re-used animals in column 1.7 should be excluded from the total in the column 1.2

TABLE 2: NUMBER OF ANIMALS USED IN EXPERIMENTS FOR SELECTED PURPOSES

Purpose versus species

	2.1	2.2	2.3	2.4	2.5	2.6	2.7	2.8	2.9	2.10
	Species	Biological	Research and	Production and	Production and	Toxicological and	Diagnosis of	Education	Other	Total
		studies of a	development of	quality control of	quality control	other safety	disease	and training		
		fundamenta	products and devices	products and	of products and	evaluations				
		l nature	for human medicine	devices for human	devices for	(including safety				
			and dentistry and for	medicine and	veterinary	evaluation of				
			veterinary medicine	dentistry	medicine	products and				
			(excluding			devices for human				
			toxicological and other			medicine and				
			safety evaluations			dentistry and for				
			counted in column 2.6)			veterinary				
2 -	Mice	F 40 C 40	277 287	106 512	42 650	medicine) 50 280	1 111	16 146	38 423	4.004.050
2.a. 2.b.	Rats	548 649 101 199	195 642	47 486	11 683	62 982	4 411 885	13 472	2 068	1 084 358 435 417
2.c.	Guinea-Pigs	1 907	4 999	14 251	5 921	9 755	11	402	515	37 761
2.d.	Hamsters	3 583	2 227	3	1 195	56	6	307	539	7 916
	Other Rodents	3 161	3 901	0	0	0	6	186	368	7 622
2.e. 2.f.	Rabbits	2 600	7 083	81 097	5 204	4 568	1 188	194	1 395	103 329
	Cats	293	490	35	38	128	3	134	23	1 023
2.g.			1 568		245		63	89	37	
2.h.	Dogs	410		34		2 422				4 868
2.i.	Ferrets	4	542	0	0	0	0	0	14	560
2.j.	Other Carnivores	27	0	0	202	0	0	0	6	235
2.k.	Horses, donkeys and cross	385	202	0	2	10	54	102	0	755
2.1	breds Pigs	3 140	4 845	32	985	327	925	1 978	934	13 166
2.1.	Goats	151	4 645	7	965	2	925	55	13	275
2.m.		882	583	54	101	2	359	104	1 432	3 517
2.n.	Sheep Cattle	435	1 159	0	147	91	734	161	182	2 909
2.0.	Prosimians	435		0		97				
2.p.		196	0	0	0	122	0	0	0	99
2.q.	New World Monkeys		89		0		0	0	•	408
2.r.	Old World Monkeys	51	158	0	0	1 299		8	63	1 579
2.s.	Apes	0	0	0	0	0	0	0	0	0
2.t.	Other Mammals	107	7	0	0	0	0	1	0	115
2.u.	Quail	0	0	0	0	2 447	0	0	10	2 457
2.v.	Other birds	9 089	10 329	690	13 117	1 644	857	1 271	2 153	39 150
2.w.	Reptiles	114	13	0	0	0	0	9	0	136
2.x.	Amphibians	8 836	0	0	0	0	0	1 596	0	10 432
2.y.	Fish	30 135	0	0	825	23 180	4 156	2 177	3 864	64 337
2.z.	TOTAL	715 356	511 167	250 201	82 316	159 412	13 661	38 271	52 040	1 822 424

TABLE 3: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS

Products versus species

	3.1	3.2	3.3	3.4	3.5	3.6	3.7	3.8	3.9	3.10	3.11
	Species	Products/	Products/	Products/	Products/	Products/	Products/	Products/	Potential or	Other toxico-	Total
	-	substances or	substances	substances	substances	substances	substances	substances	actual contami-	logical or	
		devices for	used or	used or	used or	used or	used or	used or	nents in the	safety	
		human	intended to	intended to	intended to	intended to	intended to be	intended to be	general envi-	evaluations	
		medicine and	be used	be used	be used	be used	used mainly	used mainly	ronment which		
		dentistry and	mainly in	mainly in	mainly in	mainly as	as additives in	as additives in	do not appear in		
		for veterinary	agriculture	industry	the	cosmetics	food for	food for	other columns		
		medicine			household	or toiletries	human	animal			
							consumption	consumption			
3.a.	Mice	32 474	6 930	10 388	0	0	0	0	10	478	50 280
3.b.	Rats	36 143	10 131	15 018	113	0	0	0	451	1 126	62 982
3.c.	Guinea-Pigs	5 364	2 290	2 061	0	0	0	0	0	40	9 755
3.d.	Hamsters	36	20	0	0	0	0	0	0	0	56
3.e.	Other Rodents	0	0	0	0	0	0	0	0	0	0
3.f.	Rabbits	3 182	851	501	4	0	0	0	0	30	4 568
3.g.	Cats	128	0	0	0	0	0	0	0	0	128
3.h.	Dogs	2 135	184	103	0	0	0	0	0	0	2 422
3.i.	Ferrets	0	0	0	0	0	0	0	0	0	0
3.j.	Other Carnivores	0	0	0	0	0	0	0	0	0	0
3.k.	Horses, donkeys and cross breds	10	0	0	0	0	0	0	0	0	10
3.1.	Pigs	303	0	8	0	0	0	0	0	16	327
3.m.	Goats	0	2	0	0	0	0	0	0	0	2
3.n.	Sheep	2	0	0	0	0	0	0	0	0	2
3.o.	Cattle	91	0	0	0	0	0	0	0	0	91
3.p.	Prosimians	97	0	0	0	0	0	0	0	0	97
3.q.	New World Monkeys	122	0	0	0	0	0	0	0	0	122
3.r.	Old World Monkeys	1 299	0	0	0	0	0	0	0	0	1 299
3.s.	Apes	0	0	0	0	0	0	0	0	0	0
3.t.	Other Mammals	0	0	0	0	0	0	0	0	0	0
3.u.	Quail	0	2 447	0	0	0	0	0	0	0	2 447
3.v.	Other birds	60	1 084	0	0	0	0	480	20	0	1 644
3.w.	Reptiles	0	0	0	0	0	0	0	0	0	0
3.x.	Amphibians	0	0	0	0	0	0	0	0	0	0
3.y.	Fish	313	8 521	2 664	0	0	0	0	9 744	1 938	23 180
3.z.	TOTAL	81 759	32 460	30 743	117	0	0	480	10 225	3 628	159 412

TABLE 4: NUMBER OF ANIMALS USED IN EXPERIMENTS FOR STUDIES ON HUMAN AND ANIMAL DISEASES

Main categories versus species

	4.1	4.2	4.3	4.4	4.5	4.6	4.7
	Species	Human cardiovascular	Human nervous and	Human cancer (excluding	Other human diseases	Studies specific to animal	Total
		diseases	mental disorders	evaluations of carcinogenic		diseases	
				hazards or risks)			
4.a.	Mice	53 032	131 336	161 390	361 742	3 918	711 418
4.b.	Rats	45 836	110 443	9 632	110 670	289	276 870
4.c.	Guinea-Pigs	614	289	37	4 777	144	5 861
4.d.	Hamsters	661	1 783	182	2 426	0	5 052
4.e.	Other Rodents	10	1 006	362	3 615	634	5 627
4.f.	Rabbits	4 559	221	124	2 725	480	8 109
4.g.	Cats	0	60	0	28	360	448
4.h.	Dogs	543	3	28	195	955	1 724
4.i.	Ferrets	0	0	0	533	0	533
4.j.	Other Carnivores	0	0	0	0	0	0
4.k.	Horses, donkeys and cross breds	0	0	8	16	451	475
4.1.	Pigs	2 156	172	118	1 677	2 368	6 491
4.m.	Goats	15	1	3	6	12	37
4.n.	Sheep	375	9	0	253	933	1 570
4.o.	Cattle	0	43	0	142	1 884	2 069
4.p.	Prosimians	0	0	0	0	0	0
4.q.	New World Monkeys	16	105	2	129	0	252
4.r.	Old World Monkeys	3	18	2	96	0	119
4.s.	Apes	0	0	0	0	0	0
4.t.	Other Mammals	0	7	0	42	0	49
4.u.	Quail	0	0	0	0	0	0
4.v.	Other birds	0	8	0	915	10 965	11 888
4.w.	Reptiles	13	0	0	12	78	103
4.x.	Amphibians	561	131	16	239	0	947
4.y.	Fish	300	593	0	2 000	6 756	9 649
4.z.	TOTAL	108 694	246 228	171 904	492 238	30 227	1 049 291

TABLE 5: NUMBER OF ANIMALS USED IN PRODUCTION AND QUALITY CONTROL OF PRODUCTS AND DEVICES FOR HUMAN MEDICINE AND DENTISTRY AND FOR VETERINARY MEDICINE

Regulatory requirements versus species

	5.1	5.2	5.3	5.4	5.5	E (<i>c</i> 7	
	Ci			= -		5.6	5.7	5.8
	Species	National legislation	EC legislation	Member Country of Council	Other legislation	Any combination of	No regulatory	Total
		specific to a single EC	including European	of Europe (but not EC)		5.2/ 5.3/ 5.4/ 5.5	requirements	
		Member State	Pharmacopoeia	legislation				
		1)	(requirements)	2)				
5.a.	Mice	391	110 626	0	872	33 610	3 663	149 162
5.b.	Rats	0	52 998	0	0	5 874	297	59 169
5.c.	Guinea-Pigs	0	16 475	0	436	3 125	136	20 172
5.d.	Hamsters	0	859	0	0	275	64	1 198
5.e.	Other Rodents	0	0	0	0	0	0	0
5.f.	Rabbits	0	52 271	0	0	8 292	25 738	86 301
5.g.	Cats	0	73	0	0	0	0	73
5.h.	Dogs	0	245	0	0	34	0	279
5.i.	Ferrets	0	0	0	0	0	0	0
5.j.	Other Carnivores	0	202	0	0	0	0	202
5.k.	Horses, donkeys and cross breds	0	2	0	0	0	0	2
5.1.	Pigs	15	948	0	0	0	54	1 017
5.m.	Goats	0	4	0	0	1	3	8
5.n.	Sheep	0	15	0	0	79	61	155
5.0.	Cattle	0	128	0	0	17	2	147
5.p.	Prosimians	0	0	0	0	0	0	0
5.q.	New World Monkeys	0	0	0	0	0	0	0
5.r.	Old World Monkeys	0	0	0	0	0	0	0
5.s.	Apes	0	0	0	0	0	0	0
5.t.	Other Mammals	0	0	0	0	0	0	0
5.u.	Quail	0	0	0	0	0	0	0
5.v.	Other birds	863	1 931	0	0	10 963	50	13 807
5.w.	Reptiles	0	0	0	0	0	0	0
5.x.	Amphibians	0	0	0	0	0	0	0
5.y.	Fish	0	825	0	0	0	0	825
5.z.	TOTAL	1 269	237 602	0	1 308	62 270	30 068	332 517

Examples: 5.2 – France is testing due to a UK (or FR) specific requirement

5.3 - UK is testing according to EC legislation

5.4 – Spain is testing due to a Hungarian requirement

5.5 – Sweden is testing due to a US specific requirement

5 of the country testing due to a competitive requirement

5.6 – Germany is testing due to a Czech requirement (also an EC requirement)

Footnotes: 1) EC

Note: columns 5.2 - 5.5 refer to the legislation imposing that the test be carried out and

not to the body which has issued the actual test method, guideline or protocol.

a test required by French legislation and carried out in Belgium according to an

ISO protocol must be coded as a national (FR) legislative requirement and be

entered into column 5.2 in the tables submitted by Belgium.

- 1) EC Member States: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden, United Kingdom
- 2) Member Countries of Council of Europe (non-EC): Albania, Andorra, Bulgaria, Croatia, Cyprus, Czech Rep., Estonia, Hungary, Iceland, Latvia, Liechtenstein, Lithuania, Malta, Moldova, Norway, Poland, Romania, Russia, San Marino, Slovakia, Slovenia, Switzerland, 'the former Yugoslav Rep. of Macedonia', Turkey, Ukraine

Example:

TABLE 6: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS

Regulatory requirements versus species

	6.1	6.2	6.3	6.4	6.5	6.6	6.7	6.8
	Species	National legislation	EC legislation	Member Country of Council	Other legislation	Any combination of	No regulatory	Total
	1	specific to a single EC	including European	of Europe (but not EC)	S	6.2/ 6.3/ 6.4/ 6.5	requirements	
		Member State	Pharmacopoeia	legislation			ī	
		1)	(requirements)	2)				
6.a.	Mice	0	33 677	0	4 357	10 625	1 621	50 280
6.b.	Rats	374	35 528	0	584	24 122	2 374	62 982
6.c.	Guinea-Pigs	0	7 055	0	20	2 487	193	9 755
6.d.	Hamsters	0	56	0	0	0	0	56
6.e.	Other Rodents	0	0	0	0	0	0	0
6.f.	Rabbits	0	3 484	0	0	1 034	50	4 568
6.g.	Cats	102	22	0	0	4	0	128
6.h.	Dogs	64	999	0	0	1 347	12	2 422
6.i.	Ferrets	0	0	0	0	0	0	0
6.j.	Other Carnivores	0	0	0	0	0	0	0
6.k.	Horses, donkeys and cross breds	0	0	0	0	0	10	10
6.1.	Pigs	0	139	0	0	172	16	327
6.m.	Goats	0	2	0	0	0	0	2
6.n.	Sheep	0	2	0	0	0	0	2
6.0.	Cattle	0	91	0	0	0	0	91
6.p.	Prosimians	0	97	0	0	0	0	97
6.q.	New World Monkeys	0	0	0	0	122	0	122
6.r.	Old World Monkeys	0	0	0	0	1 299	0	1 299
6.s.	Apes	0	0	0	0	0	0	0
6.t.	Other Mammals	0	0	0	0	0	0	0
6.u.	Quail	0	1 562	0	0	885	0	2 447
6.v.	Other birds	0	1 213	0	0	351	80	1 644
6.w.	Reptiles	0	0	0	0	0	0	0
6.x.	Amphibians	0	0	0	0	0	0	0
6.y.	Fish	4 770	5 653	0	0	9 865	2 892	23 180
6.z.	TOTAL	5 310	89 580	0	4 961	52 313	7 248	159 412

Examples:

6.2 – France is testing due to a UK (or FR) specific requirement

6.3 - UK is testing according to EC legislation

6.4 – Spain is testing due to a Hungarian requirement

6.5 – Sweden is testing due to a US specific requirement

6.6 - Germany is testing due to a Czech requirement (also an EC

requirement)

Note:

Example:

columns 6.2 - 6.5 refer to the legislation imposing that the test be carried out and not to the body which has issued the actual test method, guideline or protocol.

a test required by French legislation and carried out in Belgium according to an

ISO protocol must be coded as a national (FR) legislative requirement and be

entered into column 6.2 in the tables submitted by Belgium.

Footnotes:

1) EC Member States: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden, United Kingdom

²⁾ Member Countries of Council of Europe (non-EC): Albania, Andorra, Bulgaria, Croatia, Cyprus, Czech Rep., Estonia, Hungary, Iceland, Latvia, Liechtenstein, Lithuania, Malta, Moldova, Norway, Poland, Romania, Russia, San Marino, Slovakia, Slovenia, Switzerland, 'the former Yugoslav Rep. of Macedonia', Turkey, Ukraine

TABLE 7: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS

Types of tests versus species

	7.1 Species	7.2 Acute and sub-acute toxicity testing methods (including limit test)			7.3 Skin irritation	7.4 Skin sensitisatio	7.5 Eye irritation	7.6 Sub- chronic and	7.7 Carcino- genicity	7.8 Develop- mental	7.9 Muta- genicit	7.10 Repro- ductive	7.11 Toxicity to aquatic	7.12 Other	7.13 Total
						n		chronic toxicity		toxicity	у	toxicity	vertebra- tes not included in other		
		7.2.1. LD50, LC50	7.2.2 Other lethal methods	7.2.3 Non lethal clinical signs									columns		
7	NC.	0	22.077	methods	4.057	40.005	4.004	50,000	0	22.077	0	4.057	40.005	4.004	FO 200
7.a. 7.b.	Mice Rats	0 374	33 677 35 528	0	4 357 584	10 625 24 122	1 621 2 374	50 280 62 982	0 374	33 677 35 528	0	4 357 584	10 625 24 122	1 621 2 374	50 280 62 982
7.c.	Guinea-Pigs	0	7 055	0	20	2 487	193	9 755	0	7 055	0	20	2 487	193	9 755
7.d.	Hamsters	0	56	0	0	0	0	56	0	56	0	0	0	0	56
7.e.	Other Rodents	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.f.	Rabbits	0	3 484	0	0	1 034	50	4 568	0	3 484	0	0	1 034	50	4 568
7.g.	Cats	102	22	0	0	4	0	128	102	22	0	0	4	0	128
7.h.	Dogs	64	999	0	0	1 347	12	2 422	64	999	0	0	1 347	12	2 422
7.i.	Ferrets	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.j.	Other Carnivores	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.k.	Horses, donkeys and cross breds	0	0	0	0	0	10	10	0	0	0	0	0	10	10
7.1.	Pigs	0	139	0	0	172	16	327	0	139	0	0	172	16	327
7.m.	Goats	0	2	0	0	0	0	2	0	2	0	0	0	0	2
7.n.	Sheep	0	2	0	0	0	0	2	0	2	0	0	0	0	2
7.o.	Cattle	0	91	0	0	0	0	91	0	91	0	0	0	0	91
7.p.	Prosimians	0	97	0	0	0	0	97	0	97	0	0	0	0	97
7.q.	New World Monkeys	0	0	0	0	122	0	122	0	0	0	0	122	0	122
7.r.	Old World Monkeys	0	0	0	0	1 299	0	1 299	0	0	0	0	1 299	0	1 299
7.s.	Apes	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.t.	Other Mammals	0	0	0	0	0	0	0	0	0	0	0	0	0	0 447
7.u. 7.v.	Quail Other birds	0	1 562 1 213	0	0	885 351	0 80	2 447 1 644	0	1 562 1 213	0	0	885 351	0 80	2 447 1 644
7.v.	Reptiles	0	1 213	0	0	351	80 0	0	0	1 213	0	0	0	0	1 644
7.w.	Amphibians	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.x. 7.y.	Fish	4 770	5 653	0	0	9 865	2 892	23 180	4 770	5 653	0	0	9 865	2 892	23 180
7.y. 7.z.	TOTAL	5 310	89 580	0	4 961	52 313	7 248	159 412	5 310	89 580	0	4 961	52 313	7 248	159 412

TABLE 8: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS

Types of tests versus products

	8.1 Products	Acute and sub-acute toxicity testing methods (including limit test) 8.2.1. 8.2.2 8.2.3		8.3 Skin irritation	8.4 Skin sensitisatio n	Skin Eye nsitisatio irritation	Eye Sub-	8.7 Carcino genicity	Develop- M mental ge	8.9 Muta- genicit y	8.10 Reproductive toxicity	8.11 Toxicity to aquatic vertebra- tes not included in other columns	8.12 Other	8.13 Total	
		LD50, LC50	Other lethal methods	Non lethal clinical signs methods											
8.a.	Products/substances or devices for human medicine and dentistry and for veterinary medicine	0	33 677	0	4 357	10 625	1 621	50 280	0	33 677	0	4 357	10 625	1 621	50 280
8.b.	Products/substances used or intended to be used mainly in agriculture	374	35 528	0	584	24 122	2 374	62 982	374	35 528	0	584	24 122	2 374	62 982
8.c.	Products/substances used or intended to be used mainly in industry	0	7 055	0	20	2 487	193	9 755	0	7 055	0	20	2 487	193	9 755
8.d.	Products/substances used or intended to be used mainly in the household	0	56	0	0	0	0	56	0	56	0	0	0	0	56
8.e.	Products/substances used or intended to be used mainly as cosmetics or toiletries	0	0	0	0	0	0	0	0	0	0	0	0	0	0
8.f.	Products/substances used or intended to be used mainly as additives in food for human consumption	0	3 484	0	0	1 034	50	4 568	0	3 484	0	0	1 034	50	4 568
8.g.	Products/substances used or intended to be used mainly as additives in food for animal consumption	102	22	0	0	4	0	128	102	22	0	0	4	0	128
8.h.	Potential or actual contaminants in the general environment which do not appear in other columns	64	999	0	0	1 347	12	2 422	64	999	0	0	1 347	12	2 422
8.i.	Other toxicological or safety evaluations	0	0	0	0	0	0	0	0	0	0	0	0	0	0
8.j.	TOTAL	0	0	0	0	0	0	0	0	0	0	0	0	0	0

ESTONIA

Statistical data submitted

The statistical data have been submitted by anneli.harmson@agri.ee

Remark: data were reported in table 1, 2 and 4 only.

Comments of Estonian authorities

None

TABLE 1: NUMBER OF ANIMALS USED IN RELATION TO THEIR PLACE OF ORIGIN

Origin versus species

1	1.1	1.2	1.3	1.4	1.5	1.6	1.7
	Species	Total	Animals coming from registered	Animals coming from	Animals coming from	Animals coming from	Re-used animals
	Species	10141	breeding or supplying	elsewhere in the EC	Member Countries of the	other origins	re used diffinals
			establishments within the reporting	cisewhere in the EC	Council of Europe which are	other origins	
			country		parties to the Convention ETS		
					123 (excluding EC Member		
					States)		
1.a.	Mice (Mus musculus)	4350	510	3460	0	380	
1.b.	Rats (Rattus norvegicus)	484	0	484	0	0	
1.c.	Guinea-Pigs (Cavia porcellus)	0					
1.d.	Hamsters (Mesocricetus)	0					
1.e.	Other Rodents (other Rodentia)	0					
1.f.	Rabbits (Oryctolagus cuniculus)	66	0	66	0	0	0
1.g.	Cats (Felis catus)	0					
1.h.	Dogs (Canis familiaris)	0					
1.i.	Ferrets (Mustela putorius furo)	0					
1.j.	Other Carnivores (other Carnivora)	0					
1.k.	Horses, donkeys and cross breds (Equidae)	0					
1.1.	Pigs (Sus)						
1.m.	Goats (Capra)	0					
1.n.	Sheep (Ovis)						
1.o.	Cattle (Bos)	0					
1.p.	Prosimians (Prosimia)	0					
1.q.	New World Monkeys (Ceboidea)	0					
1.r.	Old World Monkeys (Cercopithecoidea)	0					
1.s.	Apes (Hominoidea)	0					
1.t.	Other Mammals (other Mammalia)						
1.u.	Quail (Coturnix coturnix)	0					
1.v.	Other birds (other Aves)						
1.w.	Reptiles (Reptilia)						
1.x.	Amphibians (Amphibia)						
1.y.	Fish (Pisces)						
1.z.	TOTAL	4900					

Note 1: Column 1.5 concerns only those Member Countries of the Council of Europe which, at the beginning of the reporting period, are Parties to the Convention ETS 123. Thus an updated list of those countries has to be used when filling in this column.

Note 2: Only the white boxes need to be completed.

Note 3: The number of re-used animals in column 1.7 should be excluded from the total in the column 1.2

TABLE 2: NUMBER OF ANIMALS USED IN EXPERIMENTS FOR SELECTED PURPOSES

Purpose versus species

					i pose vei sus s					
	2.1	2.2	2.3	2.4	2.5	2.6	2.7	2.8	2.9	2.10
	Species	Biological	Research and	Production and	Production and	Toxicological	Diagnosis of	Education and	Other	Total
	•	studies of a	development of	quality control of	quality control of	and other safety	disease	training		
		fundamenta	products and	products and	products and	evaluations				
		1 nature	devices for human	devices for	devices for	(including				
			medicine and	human medicine	veterinary	safety				
			dentistry and for	and dentistry	medicine	evaluation of				
			veterinary			products and				
			medicine			devices for				
			(excluding			human				
			toxicological and			medicine and				
			other safety			dentistry and				
			evaluations			for veterinary				
			counted in column			medicine)				
			2.6)							
2.a.	Mice	200	4150							4350
2.b.	Rats		484							484
2.c.	Guinea-Pigs									0
2.d.	Hamsters									0
2.e.	Other Rodents									0
2.f.	Rabbits		66							66
2.g.	Cats									0
2.h.	Dogs									0
2.i.	Ferrets									0
2.j.	Other Carnivores									0
2.k.	Horses, donkeys and cross									0
	breds									
2.1.	Pigs									0
2.m.	Goats									0
2.n.	Sheep									0
2.0.	Cattle									0
2.p.	Prosimians									0
2.p. 2.q.	New World Monkeys									0
2.q. 2.r.	Old World Monkeys									0
2.s.										0
2.s. 2.t.	Apes Other Mammals									0
2.u.	Quail									0
2.v.	Other birds									0
2.w.	Reptiles									0
2.x.	Amphibians									0
2.y.	Fish									0
2.z.	TOTAL	200	4700	0	0	0	0	0	0	4900

TABLE 4: NUMBER OF ANIMALS USED IN EXPERIMENTS FOR STUDIES ON HUMAN AND ANIMAL DISEASES

Main categories versus species

	4.1	4.2	4.3	4.4	4.5	4.6	4.7
	Species	Human cardiovascular	Human nervous and	Human cancer (excluding	Other human diseases	Studies specific to animal	Total
		diseases	mental disorders	evaluations of carcinogenic		diseases	
				hazards or risks)			
4.a.	Mice	340	2300	1070	640		4350
4.b.	Rats	14	320		150		484
4.c.	Guinea-Pigs						0
4.d.	Hamsters						0
4.e.	Other Rodents						0
4.f.	Rabbits	66					66
4.g.	Cats						0
4.h.	Dogs						0
4.i.	Ferrets						0
4.j.	Other Carnivores						0
4.k.	Horses, donkeys and cross breds						0
4.1.	Pigs						0
4.m.	Goats						0
4.n.	Sheep						0
4.o.	Cattle						0
4.p.	Prosimians						0
4.q.	New World Monkeys						0
4.r.	Old World Monkeys						0
4.s.	Apes						0
4.t.	Other Mammals						0
4.u.	Quail						0
4.v.	Other birds						0
4.w.	Reptiles						0
4.x.	Amphibians						0
4.y.	Fish						0
4.z.	TOTAL	420	2620	1070	790	0	4900

GREECE

Statistical data submitted

The statistical data have been submitted by the "Y Π OYP Γ EIO Γ E Ω P Γ IA Σ Γ ENIKH Δ /N Σ H KTHNIATPIKH Σ " (Ministry of Rural Development and Food, Directorate for Veterinary Care, Drugs & Practice).

Comments of Greek authorities

The legal basis for the collection of statistics on the number and use of vertebrate animals for experimental and other scientific purposes in Greece is provided by:

- Presidential Decree No 160/91 (Government Gazette I 64) on the protection of animals used for experimental and other scientific purposes, in accordance with Council Directive 86/609/EEC, and
- Law No 2015/92 (Government Gazette I 30) approving the European Convention on the protection of animals used for experimental and other scientific purposes.

For the collection of statistics relating to the year 2005, the tables, data and glossary of terms set out in European Commission document EL/11/97/04100000 W00 of 24.6.1997 were used. The Ministry of Rural Development and Food, Directorate-General for Veterinary Affairs, Directorate for Veterinary Care, Drugs & Practice sent them directly to the educational establishments (universities and technological colleges), research centres, healthcare institutions and businesses and pharmaceutical companies which use vertebrate animals for experimental and other scientific purposes. These documents were not sent to cosmetics manufacturers for the year in question, as our department was informed that no cosmetics company uses animals for experimental purposes in Greece.

The total number of animals used in experiments in Greece in 2005 was 926 094.

Of these, 97.32% (901°300 animals) were **fish**, of which 0.14% were used to study fundamental biological characteristics and 99.86% for research and development of medical, dental and veterinary products and appliances (not including toxicological studies).

A further 2.374% (21 978 animals) were **rodents** (15 340 mice – accounting for 69.79%, 6 024 rats - accounting for 27.4%, 574 guinea pigs – accounting for 2.61% and 40 other rodents – accounting for 0.18%), 36.95% of which were used to study fundamental biological characteristics, 18.48% for research and development of medical, dental and veterinary products and appliances, 0.59% to control the production and quality of medical and dental products and appliances, 25.2% for toxicological and other safety studies (exclusively rats in this case), 14.84% for diagnosing illnesses, 0.01% for education and training purposes and, finally, 0.019% for other purposes.

<u>Rabbits</u> accounted for 0.13% of the animals used: (1 255 animals, of which 10 had already been used to take blood samples for the purpose of isolating platelets for further laboratory trials) 48.44% were used to study fundamental biological characteristics, 2.78% for research and development of medical, dental and veterinary products and appliances, 1.59% to control the production and quality of medical and dental products and appliances, 9.32% to control

the production and quality of veterinary products and appliances, 0.95% for toxicological and other safety studies, 2.23% for the diagnosis of illnesses, 16.09% for education and training purposes and, finally, 18.56% for other purposes.

<u>Dogs</u> accounted for 0.0015% (14 animals), of which 71.42% were used for research and development of medical, dental and veterinary products and appliances and 28.58% for education and training purposes.

Pigs accounted for 0.048% of the animals used (448 animals), of which 25.67% were used to study fundamental biological characteristics, 11.16% for research and development of medical, dental and veterinary products and appliances, 59.37% for education and training purposes and, finally, 3.79% for other purposes.

Sheep accounted for 0.001% of the animals used (99 animals), of which 20.2% were used to study fundamental biological characteristics, 54.54% for the diagnosis of illnesses, 24.24% for education and training purposes and 1.01% for other purposes.

Three Old World Apes were used to study fundamental biological characteristics, of which two can be reused according to the research institution's statement.

<u>Hens</u> accounted for 0.002% (21 animals), of which 71.42% were used for the diagnosis of diseases and 28.58% for education and training purposes.

<u>Amphibians</u> accounted for 0.105% (975 animals), of which 100% were used for education and training purposes.

Finally, only one (1) equid was used for education and training purposes.

It is apparent from the above data that the two main categories of experiments conducted in Greece are on the one hand, research and development of medical, dental and veterinary products and appliances and on the other, the study of fundamental biological characteristics.

More specifically, vertebrate animals are principally used:

- for research programmes in Greece's Higher Education Institutions and research centres. In particular, a high percentage of fish endemic to the waters of the Mediterranean Sea are used (the main source of the large number of fish referred to above).
- to study each species' fundamental biological characteristics, for which mainly rodents (mice and rats) and rabbits are used.

HEAD OF THE DIRECTORATE FOR VETERINARY CARE, DRUGS & PRACTICE

I. PAPADOPOULOS

TABLE 1: NUMBER OF ANIMALS USED IN RELATION TO THEIR PLACE OF ORIGIN

Origin versus species

1.1 Species	1.2 Total	1.3 Animals coming from registered breeding or supplying establishments within the reporting country	1.4 Animals coming from elsewhere in the EC	1.5 Animals coming from Member Countries of the Council of Europe which are parties to the Convention ETS 123 (excluding EC Member	1.6 Animals coming from other origins	1.7 Re-used animals
				States)		
1.a. Mice (Mus musculus)	15340	14050	80		1210	_
1.b. Rats (Rattus norvegicus)	6024	5892			132	
1.c. Guinea-Pigs (Cavia porcellus)	574	324			250	
1.d. Hamsters (Mesocricetus)	0					
1.e. Other Rodents (other <i>Rodentia</i>)	40					
1.f. Rabbits (Oryctolagus cuniculus)	1255	1255				10
1.g. Cats (Felis catus)	0					
1.h. Dogs (Canis familiaris)	14	6	8			
1.i. Ferrets (Mustela putorius furo)	0					
1.j. Other Carnivores (other <i>Carnivora</i>)						
1.k. Horses, donkeys and cross breds (<i>Equidae</i>)	1					
1.1. Pigs (Sus)	448					
1.m. Goats (Capra)						
1.n. Sheep (Ovis)	99					
1.o. Cattle (Bos)						
1.p. Prosimians (<i>Prosimia</i>)	0					
1.q. New World Monkeys (Ceboidea)	0					
1.r. Old World Monkeys (Cercopithecoidea)	1		1			2
1.s. Apes (Hominoidea)	0					_
1.t. Other Mammals (other Mammalia)						
1.u. Quail (Coturnix coturnix)	0					
1.v. Other birds (other <i>Aves</i>)	21					
1.w. Reptiles (Reptilia)						
1.x. Amphibians (Amphibia)	975					
1.y. Fish (Pisces)	901300					
1.z. TOTAL	926092					

Note 1: Column 1.5 concerns only those Member Countries of the Council of Europe which, at the beginning of the reporting period, are Parties to the Convention ETS 123. Thus an updated list of those countries has to be used when filling in this column.

Note 2: Only the white boxes need to be completed.

Note 3: The number of re-used animals in column 1.7 should be excluded from the total in the column 1.2

TABLE 2: NUMBER OF ANIMALS USED IN EXPERIMENTS FOR SELECTED PURPOSES

Purpose versus species

	2.1	2.2	2.3	2.4	2.5	2.6	2.7	2.8	2.9	2.10
	Species	Biological	Research and	Production and	Production and	Toxicological	Diagnosis of	Education and	Other	Total
	•	studies of a	development of	quality control of	quality control of	and other safety	disease	training		
		fundamenta	products and	products and	products and	evaluations		· ·		
		l nature	devices for human	devices for	devices for	(including				
			medicine and	human medicine	veterinary	safety				
			dentistry and for	and dentistry	medicine	evaluation of				
			veterinary			products and				
			medicine			devices for				
			(excluding			human				
			toxicological and			medicine and				
			other safety evaluations			dentistry and for veterinary				
			counted in column			medicine)				
			2.6)			incurcinc)				
2.a.	Mice	3279	3382	50		5324	2956	138	211	15340
2.b.	Rats	4629	641	80		144	37	280	213	6024
2.c.	Guinea-Pigs	215				85	270	4		574
2.d.	Hamsters									0
2.e.	Other Rodents		40							40
2.f.	Rabbits	608	35	20	117	12	28	202	233	1255
2.g.	Cats									0
2.h.	Dogs		10					4		14
2.i.	Ferrets									0
2.j.	Other Carnivores									0
2.k.	Horses, donkeys and cross							1		1
	breds									
2.1.	Pigs	115	50					266	17	448
2.m.	Goats									0
2.n.	Sheep	20					54	24	1	99
2.0.	Cattle									0
2.p.	Prosimians									0
2.q.	New World Monkeys									0
2.r.	Old World Monkeys	1								1
2.s.	Apes									0
2.t.	Other Mammals									0
2.u.	Quail									0
2.v.	Other birds						15	6		21
2.w.	Reptiles									0
2.x.	Amphibians							975		975
2.y.	Fish	1300	900000							901300
2.z.	TOTAL	10167	904158	150	117	5565	3360	1900	675	926092

TABLE 3: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS

Products versus species

	3.1	3.2	3.3	3.4	3.5	3.6	3.7	3.8	3.9	3.10	3.11
	Species	Products/	Products/	Products/	Products/	Products/	Products/	Products/	Potential or	Other toxico-	Total
		substances or	substances	substances	substances	substances	substances	substances	actual contami-	logical or	
		devices for	used or	used or	used or	used or	used or	used or	nents in the	safety	
		human	intended to	intended to	intended to	intended to	intended to be	intended to be	general envi-	evaluations	
		medicine and	be used	be used	be used	be used	used mainly	used mainly	ronment which		
		dentistry and	mainly in	mainly in	mainly in	mainly as	as additives in	as additives in	do not appear in		
		for veterinary	agriculture	industry	the	cosmetics	food for	food for	other columns		
		medicine			household	or toiletries	human	animal			
							consumption	consumption			
3.a.	Mice	105								5219	5324
3.b.	Rats		84	60							144
3.c.	Guinea-Pigs	85									85
3.d.	Hamsters										0
3.e.	Other Rodents										0
3.f.	Rabbits									12	12
3.g.	Cats										0
3.h.	Dogs										0
3.i.	Ferrets										0
3.j.	Other Carnivores										0
3.k.	Horses, donkeys and cross breds										0
3.1.	Pigs										0
3.m.	Goats										0
3.n.	Sheep										0
3.o.	Cattle										0
3.p.	Prosimians										0
3.q.	New World Monkeys										0
3.r.	Old World Monkeys										0
3.s.	Apes										0
3.t.	Other Mammals										0
3.u.	Ouail										0
3.v.	Other birds										0
3.w.	Reptiles										0
3.x.	Amphibians										0
3.y.	Fish										0
3.z.	TOTAL	190	84	60	0	0	0	0	0	5231	5565

TABLE 4: NUMBER OF ANIMALS USED IN EXPERIMENTS FOR STUDIES ON HUMAN AND ANIMAL DISEASES

Main categories versus species

	4.1	4.2	4.3	4.4	4.5	4.6	4.7
	Species	Human cardiovascular	Human nervous and	Human cancer (excluding	Other human diseases	Studies specific to animal	Total
		diseases	mental disorders	evaluations of carcinogenic		diseases	
				hazards or risks)			
4.a.	Mice	95	1458	410	2950	300	5213
4.b.	Rats	65	102		814		981
4.c.	Guinea-Pigs					270	270
4.d.	Hamsters						0
4.e.	Other Rodents			40			40
4.f.	Rabbits	162			321	28	511
4.g.	Cats						0
4.h.	Dogs						0
4.i.	Ferrets						0
4.j.	Other Carnivores						0
4.k.	Horses, donkeys and cross breds						0
4.1.	Pigs	36			79		115
4.m.	Goats						0
4.n.	Sheep					54	54
4.o.	Cattle						0
4.p.	Prosimians						0
4.q.	New World Monkeys						0
4.r.	Old World Monkeys						0
4.s.	Apes						0
4.t.	Other Mammals						0
4.u.	Quail						0
4.v.	Other birds					15	15
4.w.	Reptiles						0
4.x.	Amphibians						0
4.y.	Fish					900000	900000
4.z.	TOTAL	358	1560	450	4164	900667	907199

TABLE 5: NUMBER OF ANIMALS USED IN PRODUCTION AND QUALITY CONTROL OF PRODUCTS AND DEVICES FOR HUMAN MEDICINE AND DENTISTRY AND FOR VETERINARY MEDICINE

	5.1	5.2	5.3	5.4	5.5	5.6	5.7	5.8
	Species	National legislation	EC legislation	Member Country of Council	Other legislation	Any combination of	No regulatory	Total
		specific to a single EC	including European	of Europe (but not EC)		5.2/ 5.3/ 5.4/ 5.5	requirements	
		Member State	Pharmacopoeia	legislation				
		1)	(requirements)	2)				
5.a.	Mice						50	50
5.b.	Rats	80						80
5.c.	Guinea-Pigs							0
5.d.	Hamsters							0
5.e.	Other Rodents							0
5.f.	Rabbits		117				20	137
5.g.	Cats							0
5.h.	Dogs							0
5.i.	Ferrets							0
5.j.	Other Carnivores							0
5.k.	Horses, donkeys and cross breds							0
5.1.	Pigs							0
5.m.	Goats							0
5.n.	Sheep							0
5.o.	Cattle							0
5.p.	Prosimians							0
5.q.	New World Monkeys							0
5.r.	Old World Monkeys							0
5.s.	Apes							0
5.t.	Other Mammals							0
5.u.	Quail							0
5.v.	Other birds							0
5.w.	Reptiles							0
5.x.	Amphibians							0
5.y.	Fish							0
5.z.	TOTAL	80	117	0	0	0	70	267

Examples:

5.2 – France is testing due to a UK (or FR) specific requirement

5.3 - UK is testing according to EC legislation

5.4 – Spain is testing due to a Hungarian requirement

5.5 – Sweden is testing due to a US specific requirement

5.6 - Germany is testing due to a Czech requirement (also an EC requirement)

Note: Example: columns 5.2 - 5.5 refer to the legislation imposing that the test be carried out and

not to the body which has issued the actual test method, guideline or protocol. a test required by French legislation and carried out in Belgium according to an

ISO protocol must be coded as a national (FR) legislative requirement and be

entered into column 5.2 in the tables submitted by Belgium.

Footnotes:

EC Member States: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden, United Kingdom

Member Countries of Council of Europe (non-EC): Albania, Andorra, Bulgaria, Croatia, Cyprus, Czech Rep., Estonia, Hungary, Iceland, Latvia, Liechtenstein, Lithuania, Malta, Moldova, Norway, Poland, Romania, Russia, San Marino, Slovakia, Slovenia, Switzerland, 'the former Yugoslav Rep. of Macedonia', Turkey, Ukraine

NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS TABLE 6:

Regulatory requirements versus species

6.1	6.2	6.3	6.4	6.5	6.6	6.7	6.8
Species	National legislation	EC legislation	Member Country of Council	Other legislation	Any combination of	No regulatory	Total
	specific to a single EC	including European	of Europe (but not EC)		6.2/ 6.3/ 6.4/ 6.5	requirements	
	Member State	Pharmacopoeia	legislation				
	1)	(requirements)	2)				
6.a. Mice		105			5219		5324
6.b. Rats	89	55					144
6.c. Guinea-Pigs		85					85
6.d. Hamsters							0
6.e. Other Rodents							0
6.f. Rabbits						12	12
6.g. Cats							0
6.h. Dogs							0
6.i. Ferrets							0
6.j. Other Carnivores							0
6.k. Horses, donkeys and cross breds							0
6.l. Pigs							0
6.m. Goats							0
6.n. Sheep							0
6.o. Cattle							0
6.p. Prosimians							0
6.q. New World Monkeys							0
6.r. Old World Monkeys							0
6.s. Apes							0
6.t. Other Mammals							0
6.u. Quail							0
6.v. Other birds							0
6.w. Reptiles							0
6.x. Amphibians							0
6.y. Fish							0
6.z. TOTAL	89	245	0	0	5219	12	5565

Examples:

6.2 – France is testing due to a UK (or FR) specific requirement

Note:

columns 6.2 - 6.5 refer to the legislation imposing that the test be carried out and

6.3 - UK is testing according to EC legislation 6.4 – Spain is testing due to a Hungarian requirement

not to the body which has issued the actual test method, guideline or protocol. a test required by French legislation and carried out in Belgium according to an

6.5 – Sweden is testing due to a US specific requirement

Example:

ISO protocol must be coded as a national (FR) legislative requirement and be

6.6 - Germany is testing due to a Czech requirement (also an EC requirement)

entered into column 6.2 in the tables submitted by Belgium.

Footnotes:

EC Member States: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden, United Kingdom

Member Countries of Council of Europe (non-EC): Albania, Andorra, Bulgaria, Croatia, Cyprus, Czech Rep., Estonia, Hungary, Iceland, Latvia, Liechtenstein, Lithuania, Malta, Moldova, Norway, Poland, Romania, Russia, San Marino, Slovakia, Slovenia, Switzerland, 'the former Yugoslav Rep. of Macedonia', Turkey, Ukraine

TABLE 7: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS

Types of tests versus species

	7.1		7.2		7.3	7.4	7.5	7.6	7.7	7.8	7.9	7.10	7.11	7.12	7.13
	Species	Acute and s	ub-acute toxicity to (including limit to	testing methods	Skin irritation	Skin sensitisatio	Eye irritation	Sub- chronic and	Carcino- genicity	Develop- mental	Muta- genicit	Repro- ductive	Toxicity to aquatic	Other	Total
			(including illinit to	251)	iiiitatioii	n	iiiitatioii	chronic	gemeny	toxicity	y	toxicity	vertebra-		
								toxicity			,		tes not		
													included		
													in other		
			ı	T									columns		,
		7.2.1.	7.2.2	7.2.3											
		LD50, LC50	Other lethal methods	Non lethal clinical signs											
		LC30	methous	methods											
7.a.	Mice		5219	methods										105	5324
7.b.	Rats			34				60			50				144
7.c.	Guinea-Pigs													85	85
7.d.	Hamsters														0
7.e.	Other Rodents														0
7.f.	Rabbits													12	12
7.g.	Cats														0
7.h.	Dogs														0
7.i.	Ferrets														0
7.j.	Other Carnivores														0
7.k.	Horses, donkeys and cross														0
	breds														
7.1.	Pigs														0
7.m.	Goats														0
7.n.	Sheep														0
7.o.	Cattle														0
7.p.	Prosimians														0
7.q.	New World Monkeys														0
7.r. 7.s.	Old World Monkeys Apes														0
7.s. 7.t.	Other Mammals														0
7.u.	Quail														0
7.u. 7.v.	Other birds														0
7.v. 7.w.	Reptiles														0
7.w.	Amphibians														0
7.y.	Fish														0
7.z.	TOTAL	0	5219	34	0	0	0	60	0	0	50	0	0	202	5565

TABLE 8: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS

Types of tests versus products

	8.1 Products		8.2 nd sub-acute toxi		8.3 Skin irritation	8.4 Skin sensitisatio	8.5 Eye irritation	8.6 Sub- chronic	8.7 Carcino	8.8 Develop-	8.9 Muta- genicit	8.10 Repro- ductive	8.11 Toxicity	8.12 Other	8.13 Total
		meun	ods (including li	mit test)	irritation	n	irritation	and chronic toxicity	genicity	mental toxicity	у	toxicity	to aquatic vertebra- tes not included in other columns		
		8.2.1. LD50, LC50	8.2.2 Other lethal methods	8.2.3 Non lethal clinical signs methods											
8.a.	Products/substances or devices for human medicine and dentistry and for veterinary medicine													202	202
8.b.	Products/substances used or intended to be used mainly in agriculture			84											84
8.c.	Products/substances used or intended to be used mainly in industry							60							60
8.d.	Products/substances used or intended to be used mainly in the household														0
8.e.	Products/substances used or intended to be used mainly as cosmetics or toiletries														0
8.f.	Products/substances used or intended to be used mainly as additives in food for human consumption														0
8.g.	Products/substances used or intended to be used mainly as additives in food for animal consumption														0
8.h.	Potential or actual contaminants in the general environment which do not appear in other columns														0
8.i.	Other toxicological or safety evaluations		5219												5219
8.j.	TOTAL	0	5219	84	0	0	0	60	0	0	0	0	0	202	5565

SPAIN

Statistical data submitted

The Statistical data have been provided by the: "Ministerio de Agricultura, Pesca y Alimentación, Subdirección General de Ordenacion de explotaciones" (Ministry of Agriculture, Fisheries and Food, Sub-directorate of Management of Developments).

Comments of Spanish authorities

None

TABLE 1: NUMBER OF ANIMALS USED IN RELATION TO THEIR PLACE OF ORIGIN

Origin versus species

1.1	1.2	1.3	1.4	1.5	1.6	1.7
Species	Total	Animals coming from registered	Animals coming from	Animals coming from	Animals coming from	Re-used animals
		breeding or supplying	elsewhere in the EC	Member Countries of the	other origins	
		establishments within the reporting		Council of Europe which are		
		country		parties to the Convention ETS		
				123 (excluding EC Member		
1.a. Mice (Mus musculus)	393217	357390	31627	States) 22	4178	
` '	125754	113623	10478	0	1653	
1.b. Rats (Rattus norvegicus)				·		
1.c. Guinea-Pigs (Cavia porcellus)	16780	14321	2459	0	0	
1.d. Hamsters (Mesocricetus)	908	877	31	0	0	
1.e. Other Rodents (other <i>Rodentia</i>)	294	4444	707			
1.f. Rabbits (Oryctolagus cuniculus)	11878	11111	767	0	0	0
1.g. Cats (Felis catus)	168	84		0	84	0
1.h. Dogs (Canis familiaris)	685	525	151	0	9	0
1.i. Ferrets (Mustela putorius furo)	237	155	82	0	0	0
1.j. Other Carnivores (other <i>Carnivora</i>)	0					
1.k. Horses, donkeys and cross breds (<i>Equidae</i>)	42					
1.l. Pigs (Sus)	4818					_
1.m. Goats (Capra)	119					
1.n. Sheep (Ovis)	821					
1.o. Cattle (<i>Bos</i>)	294					
1.p. Prosimians (<i>Prosimia</i>)	0	0	0	0	0	0
1.q. New World Monkeys (Ceboidea)	1	0	1	0	0	0
1.r. Old World Monkeys (Cercopithecoidea)	81	52	29	0	0	0
1.s. Apes (Hominoidea)	2	2	0	0	0	0
1.t. Other Mammals (other <i>Mammalia</i>)	60					
1.u. Quail (Coturnix coturnix)	1	1	0	0	0	
1.v. Other birds (other <i>Aves</i>)	8424					
1.w. Reptiles (Reptilia)	10					
1.x. Amphibians (Amphibia)	419					
1.y. Fish (<i>Pisces</i>)	30584					
1.z. TOTAL	595597	498141	45625	22	5924	0

Note 1: Column 1.5 concerns only those Member Countries of the Council of Europe which, at the beginning of the reporting period, are Parties to the Convention ETS 123. Thus an updated list of those countries has to be used when filling in this column.

Note 2: Only the white boxes need to be completed.

Note 3: The number of re-used animals in column 1.7 should be excluded from the total in the column 1.2

TABLE 2: NUMBER OF ANIMALS USED IN EXPERIMENTS FOR SELECTED PURPOSES

Purpose versus species

	2.1	2.2	2.3	2.4	2.5	2.6	2.7	2.8	2.9	2.10
	Species	Biological	Research and	Production and	Production and	Toxicological	Diagnosis of	Education and	Other	Total
		studies of a	development of	quality control of	quality control of	and other safety	disease	training		
		fundamenta	products and	products and	products and	evaluations				
		l nature	devices for human	devices for	devices for	(including				
			medicine and	human medicine	veterinary	safety				
			dentistry and for	and dentistry	medicine	evaluation of				
			veterinary			products and				
			medicine			devices for				
			(excluding toxicological and			human medicine and				
			other safety			dentistry and				
			evaluations			for veterinary				
			counted in column			medicine)				
			2.6)			medicine)				
2.a.	Mice	130339	115641	6680	17599	62528	51405	8325	11300	403817
2.b.	Rats	51885	39077	2204	810	8379	5252	5085	2843	115535
2.c.	Guinea-Pigs	342	8343	1142	3310	3510	92	28	13	16780
2.d.	Hamsters	493	52	0	264	0	87	12	0	908
2.e.	Other Rodents	100	166	0	0	0	0	28	0	294
2.f.	Rabbits	854	2674	30	2106	5026	51	1008	90	11839
2.g.	Cats	76	3	13	0	0	0	3	73	168
2.h.	Dogs	44	81	6	0	272	5	18	0	426
2.i.	Ferrets	17	220	0	0	0	0	0	0	237
2.j.	Other Carnivores	0	0	0		0	0	0	0	0
2.k.	Horses, donkeys and cross	0	0	0	42	0	0	0	0	42
	breds									
2.1.	Pigs	288	1531	0	921	368	40	1200	387	4735
2.m.	Goats	16	7	0	0	24	0	0	72	119
2.n.	Sheep	17	94	0	571	62	0	75	2	821
2.o.	Cattle	0	104	0	190	0	0	0	0	294
2.p.	Prosimians	0	0	0	0	0	0	0	0	0
2.q.	New World Monkeys	1	0	0	0	0	0	0	0	1
2.r.	Old World Monkeys	23	21	0	0	37	0	0	0	81
2.s.	Apes	2	0	0	0	0	0	0	0	2
2.t.	Other Mammals	0	0	0	60	0	0	0	0	60
2.u.	Quail	1	0	0	0	0	0	0	0	1
2.v.	Other birds	94	2682	0	4343	40	15	50	1200	8424
2.w.	Reptiles	10	0	0	0	0	0	0	0	10
2.x.	Amphibians	351	0	0	0	0	0	0	68	419
2.y.	Fish	28349	700	0	0	1269	0	266	0	30584
2.z.	TOTAL	213302	171396	10075	30216	81515	56947	16098	16048	595597

TABLE 3: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS

Products versus species

	3.1	3.2	3.3	3.4	3.5	3.6	3.7	3.8	3.9	3.10	3.11
	Species	Products/	Products/	Products/	Products/	Products/	Products/	Products/	Potential or	Other toxico-	Total
	~	substances or	substances	substances	substances	substances	substances	substances	actual contami-	logical or	
		devices for	used or	used or	used or	used or	used or	used or	nents in the	safety	
		human	intended to	intended to	intended to	intended to	intended to be	intended to be	general envi-	evaluations	
		medicine and	be used	be used	be used	be used	used mainly	used mainly	ronment which		
		dentistry and	mainly in	mainly in	mainly in	mainly as	as additives in	as additives in	do not appear in		
		for veterinary	agriculture	industry	the	cosmetics	food for	food for	other columns		
		medicine			household	or toiletries	human	animal			
							consumption	consumption			
3.a.	Mice	21400	24	0	0	0	0	725	1285	40597	64031
3.b.	Rats	3870	359	768	0	0	0	0	230	1375	6602
3.c.	Guinea-Pigs	3287	0	63	0	0	0	0	0	160	3510
3.d.	Hamsters	0	0	0	0	0	0	0	0	0	0
3.e.	Other Rodents	0	0	0	0	0	0	0	0	0	0
3.f.	Rabbits	5187	0	111	0	75	0	0	0	45	5418
3.g.	Cats	0	0	0	0	0	0	0	0	0	0
3.h.	Dogs	179	0	0	0	0	0	0	0	77	256
3.i.	Ferrets	0	0	0	0	0	0	0	0	0	0
3.j.	Other Carnivores	0	0	0	0	0	0	0	0	0	0
3.k.	Horses, donkeys and cross breds	0	0	0	0	0	0	0	0	0	0
3.1.	Pigs	251	0	0	0	0	0	0	0	15	266
3.m.	Goats	24	0	0	0	0	0	0	0	0	24
3.n.	Sheep	62	0	0	0	0	0	0	0	0	62
3.o.	Cattle	0	0	0	0	0	0	0	0	0	0
3.p.	Prosimians	0	0	0	0	0	0	0	0	0	0
3.q.	New World Monkeys	0	0	0	0	0	0	0	0	0	0
3.r.	Old World Monkeys	37	0	0	0	0	0	0	0	0	37
3.s.	Apes	0	0	0	0	0	0	0	0	0	0
3.t.	Other Mammals	0	0	0	0	0	0	0	0	0	0
3.u.	Quail	0	0	0	0	0	0	0	0	0	0
3.v.	Other birds	40	0	0	0	0	0	0	0	0	40
3.w.	Reptiles	0	0	0	0	0	0	0	0	0	0
3.x.	Amphibians	0	0	0	0	0	0	0	0	0	0
3.y.	Fish	100	237	0	560	0	0	0	372	0	1269
3.z.	TOTAL	34437	620	942	560	75	0	725	1887	42269	81515

TABLE 4: NUMBER OF ANIMALS USED IN EXPERIMENTS FOR STUDIES ON HUMAN AND ANIMAL DISEASES

Main categories versus species

	4.1	4.2	4.3	4.4	4.5	4.6	4.7
	Species	Human cardiovascular	Human nervous and	Human cancer (excluding	Other human diseases	Studies specific to animal	Total
		diseases	mental disorders	evaluations of carcinogenic		diseases	
				hazards or risks)			
4.a.	Mice	5844	13808	87612	80515	3839	191618
4.b.	Rats	5938	15263	1538	36055	579	59373
4.c.	Guinea-Pigs	44	286	110	637	325	1402
4.d.	Hamsters	0	87	52	46	143	328
4.e.	Other Rodents	0	120	0	74	448	642
4.f.	Rabbits	180	3	66	803	474	1526
4.g.	Cats	0	18	0	3	0	21
4.h.	Dogs	27	2	3	135	12	179
4.i.	Ferrets	0	0	0	0	0	0
4.j.	Other Carnivores	0	0	0	0	0	0
4.k.	Horses, donkeys and cross breds	0	17	0	0	0	17
4.1.	Pigs	273	0	21	468	420	1182
4.m.	Goats	40	24	0	7	0	71
4.n.	Sheep	0	0	0	45	55	100
4.0.	Cattle	0	0	0	0	14	14
4.p.	Prosimians	0	1	0	0	0	1
4.q.	New World Monkeys	0	3	0	0	0	3
4.r.	Old World Monkeys	0	0	0	28	0	28
4.s.	Apes	0	0	0	2	0	2
4.t.	Other Mammals	0	0	0	0	0	0
4.u.	Quail	0	57	0	0	0	57
4.v.	Other birds	0	0	0	0	1300	1300
4.w.	Reptiles	0	45	0	0	0	45
4.x.	Amphibians	0	192	50	50	0	292
4.y.	Fish	0		200	300	3966	4466
4.z.	TOTAL	12346	29926	89652	119168	11575	262667

TABLE 5: NUMBER OF ANIMALS USED IN PRODUCTION AND QUALITY CONTROL OF PRODUCTS AND DEVICES FOR HUMAN MEDICINE AND DENTISTRY AND FOR VETERINARY MEDICINE

	5.1	5.2	5.3	5.4	5.5	5.6	5.7	5.8
	Species	National legislation	EC legislation	Member Country of Council	Other legislation	Any combination of	No regulatory	Total
	-	specific to a single EC	including European	of Europe (but not EC)		5.2/ 5.3/ 5.4/ 5.5	requirements	
		Member State	Pharmacopoeia	legislation				
		1)	(requirements)	2)				
5.a.	Mice	66	21771	0	0	5	2437	24279
5.b.	Rats	0	1342	0	1672	0	0	3014
5.c.	Guinea-Pigs	0	3340	0	1058	0	54	4452
5.d.	Hamsters	0	0	0	0	0	264	264
5.e.	Other Rodents	0	0	0	0	0	0	0
5.f.	Rabbits	2	1563	0	0	0	571	2136
5.g.	Cats	0	0	0	13	0	0	13
5.h.	Dogs	0	0	0	0	0	6	6
5.i.	Ferrets	0	0	0	0	0	0	0
5.j.	Other Carnivores	0	0	0	0	0	0	0
5.k.	Horses, donkeys and cross breds	0	42	0	0	0	0	42
5.1.	Pigs	22	553	0	0	20	326	921
5.m.	Goats	0	0	0	0	0	0	0
5.n.	Sheep	0	571	0	0	0	0	571
5.o.	Cattle	0	190	0	0	0	0	190
5.p.	Prosimians	0	0	0	0	0	0	0
5.q.	New World Monkeys	0	0	0	0	0	0	0
5.r.	Old World Monkeys	0	0	0	0	0	0	0
5.s.	Apes	0	0	0	0	0	0	0
5.t.	Other Mammals	0	60	0	0	0	0	60
5.u.	Quail	0	0	0	0	0	0	0
5.v.	Other birds	0	3349	0	681	0	313	4343
5.w.	Reptiles	0	0	0	0	0	0	0
5.x.	Amphibians	0	0	0	0	0	0	0
5.y.	Fish	0	0	0	0	0	0	0
5.z.	TOTAL	90	32781	0	3424	25	3971	40291

Examples:

5.2 – France is testing due to a UK (or FR) specific requirement

5.3 - UK is testing according to EC legislation

5.4 – Spain is testing due to a Hungarian requirement

5.5 – Sweden is testing due to a US specific requirement

5.6 - Germany is testing due to a Czech requirement (also an EC

requirement)

Note:

columns 5.2 - 5.5 refer to the legislation imposing that the test be carried out and

not to the body which has issued the actual test method, guideline or protocol. a test required by French legislation and carried out in Belgium according to an

Example: ISO protocol must be coded as a national (FR) legislative requirement and be

entered into column 5.2 in the tables submitted by Belgium.

Footnotes:

EC Member States: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden, United Kingdom

Member Countries of Council of Europe (non-EC): Albania, Andorra, Bulgaria, Croatia, Cyprus, Czech Rep., Estonia, Hungary, Iceland, Latvia, Liechtenstein, Lithuania, Malta, Moldova, Norway, Poland, Romania, Russia, San Marino, Slovakia, Slovenia, Switzerland, 'the former Yugoslav Rep. of Macedonia', Turkey, Ukraine

NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS TABLE 6:

	6.1	6.2	6.3	6.4	6.5	6.6	6.7	6.8
	Species	National legislation	EC legislation	Member Country of Council	Other legislation	Any combination of	No regulatory	Total
	1	specific to a single EC	including European	of Europe (but not EC)	Č	6.2/ 6.3/ 6.4/ 6.5	requirements	
		Member State	Pharmacopoeia	legislation			1	
		1)	(requirements)	2)				
6.a.	Mice	308	13299	0	441	46381	3602	64031
6.b.	Rats	96	1195	0	1509	2391	1411	6602
6.c.	Guinea-Pigs	41	703	0	287	2479	0	3510
6.d.	Hamsters	0	0	0	0	0	0	0
6.e.	Other Rodents	0	0	0	0	0	0	0
6.f.	Rabbits	133	194	0	175	4760	156	5418
6.g.	Cats	0	0	0	0	0	23	23
6.h.	Dogs	0	67	0	10	156	0	233
6.i.	Ferrets	0	0	0	0	0	0	0
6.j.	Other Carnivores	0	0	0	0	0	0	0
6.k.	Horses, donkeys and cross breds	0	0	0	0	0	0	0
6.1.	Pigs	6	244	0	0	16	0	266
6.m.	Goats	0	24	0	0	0	0	24
6.n.	Sheep	2	42	0	0	0	18	62
6.0.	Cattle	0	0	0	0	0	0	0
6.p.	Prosimians	0	0	0	0	0	0	0
6.q.	New World Monkeys	0	0	0	0	0	0	0
6.r.	Old World Monkeys	0	0	0	0	32	5	37
6.s.	Apes	0	0	0	0	0	0	0
6.t.	Other Mammals	0	0	0	0	0	0	0
6.u.	Quail	0	0	0	0	0	0	0
6.v.	Other birds	0	0	0	0	0	40	40
6.w.	Reptiles	0	0	0	0	0	0	0
6.x.	Amphibians	0	0	0	0	0	0	0
6.y.	Fish	0	0	0	72	1197	0	1269
6.z.	TOTAL	586	15768	0	2494	57412	5255	81515

Examples:

6.2 – France is testing due to a UK (or FR) specific requirement

6.3 - UK is testing according to EC legislation

6.4 – Spain is testing due to a Hungarian requirement

6.5 – Sweden is testing due to a US specific requirement

6.6 - Germany is testing due to a Czech requirement (also an EC

requirement)

Note:

Example:

columns 6.2 - 6.5 refer to the legislation imposing that the test be carried out and

not to the body which has issued the actual test method, guideline or protocol.

a test required by French legislation and carried out in Belgium according to an ISO protocol must be coded as a national (FR) legislative requirement and be

entered into column 6.2 in the tables submitted by Belgium.

Footnotes:

EC Member States: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden, United Kingdom

Member Countries of Council of Europe (non-EC): Albania, Andorra, Bulgaria, Croatia, Cyprus, Czech Rep., Estonia, Hungary, Iceland, Latvia, Liechtenstein, Lithuania, Malta, Moldova, Norway, Poland, Romania, Russia, San Marino, Slovakia, Slovenia, Switzerland, 'the former Yugoslav Rep. of Macedonia', Turkey, Ukraine

TABLE 7: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS

Types of tests versus species

	7.1		7.2		7.3	7.4	7.5	7.6	7.7	7.8	7.9	7.10	7.11	7.12	7.13
	Species		ub-acute toxicity		Skin	Skin	Eye	Sub-	Carcino-	Develop-	Muta-	Repro-	Toxicity	Other	Total
			(including limit to	est)	irritation	sensitisatio	irritation	chronic and	genicity	mental	genicit	ductive	to aquatic		
						n		chronic toxicity		toxicity	У	toxicity	vertebra-		
								toxicity					tes not included		
													in other		
													columns		
		7.2.1.	7.2.2	7.2.3											
		LD50,	Other lethal	Non lethal											
		LC50	methods	clinical signs											
7.a.	Mice	9430	35486	methods 1016	0	40	0	0	674	0	24	0	0	17361	64031
7.b.	Rats	831	365	601	135	0	0	1057	96	0	0	567	0	2956	6608
7.c.	Guinea-Pigs	0	399	12	16	463	0	0	0	0	0	0	0	2614	3504
7.d.	Hamsters	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.e.	Other Rodents	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.f.	Rabbits	6	16	24	282	0	64	6	0	113	0	0	0	4907	5418
7.g.	Cats	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.h.	Dogs	0	0	0	0	0	0	156	0	0	0	0	0	100	256
7.i.	Ferrets	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.j.	Other Carnivores	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.k.	Horses, donkeys and cross	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	breds														
7.1.	Pigs	0	0	0	0	0	0	0	0	0	0	0	0	266	266
7.m.	Goats	0	0	0	0	0	0	0	0	0	0	0	0	24	24
7.n.	Sheep	0	0	0	0	0	0	0	0	0	0	0	0	62	62
7.o. 7.p.	Cattle Prosimians	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.p. 7.g.	New World Monkeys	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.q. 7.r.	Old World Monkeys	0	0	0	0	0	0	37	0	0	0	0	0	0	37
7.s.	Apes	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.t.	Other Mammals	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.u.	Quail	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.v.	Other birds	0	0	0	0	0	0	0	0	0	0	0	0	40	40
7.w.	Reptiles	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.x.	Amphibians	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.y.	Fish	287	0	0	0	0	0	860	0	50	0	72	0	0	1269
7.z.	TOTAL	10554	36266	1653	433	503	64	2116	770	163	24	639	0	28330	81515

TABLE 8: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS

Types of tests versus products

	8.1		8.2		8.3	8.4	8.5	8.6	8.7	8.8	8.9	8.10	8.11	8.12	8.13
	Products		nd sub-acute tox ods (including li		Skin irritation	Skin sensitisatio n	Eye irritation	Sub- chronic and chronic toxicity	Carcino genicity	Develop- mental toxicity	Muta- genicit y	Reproductive toxicity	Toxicity to aquatic vertebra- tes not included in other columns	Other	Total
		LD50, LC50	Other lethal methods	Non lethal clinical signs methods											
8.a.	Products/substances or devices for human medicine and dentistry and for veterinary medicine	2563	2749	1633	281	445	24	897	0	163	0	567	0	25115	34437
8.b.	Products/substances used or intended to be used mainly in agriculture	237	0	0	0	0	0	359	0	0	24	0	0	0	620
8.c.	Products/substances used or intended to be used mainly in industry	601	71	0	90	58	21	0	96	0	0	0	0	5	942
8.d.	Products/substances used or intended to be used mainly in the household	0	0	0	0	0	0	560	0	0	0	0	0	0	560
8.e.	Products/substances used or intended to be used mainly as cosmetics or toiletries	0	0	0	56	0	19	0	0	0	0	0	0	0	75
8.f.	Products/substances used or intended to be used mainly as additives in food for human consumption	0	0	0	0	0	0	0	0	0	0	0	0	0	0
8.g.	Products/substances used or intended to be used mainly as additives in food for animal consumption	0	725	0	0	0	0	0	0	0	0	0	0	0	725
8.h.	Potential or actual contaminants in the general environment which do not appear in other columns	473	812	6	0	0	0	300	0	0	0	72	0	224	1887
8.i.	Other toxicological or safety evaluations	6680	33075	14	6	0	0	0	674	0	0	0	0	1820	42269
8.j.	TOTAL	10554	37432	1653	433	503	64	2116	770	163	24	639	0	27164	81515

FRANCE

Statistical data submitted

The statistical data have been submitted by the "Ministère de la Recherche et des Nouvelles Technologies" (Ministry for Research and New Technologies).

Comments of the French authorities

This study was realized by the *EFICOM Markétudes* Company for the Research and University Education Ministry.

The number of animals used in France since 1999 is steady and about 2.2 billion. It represents a decrease of 40 % in comparison with the figures of the first study in 1990. In 2004, a slight increasing tendency could have been observed which led the figures to their 1999 rounded values. Since 1999, the amount of rodents used is steady (2.1 billion); and even if some animal groups are more often used (the amount of fishes and amphibian has doubled), there is a reversal tendency for other species (the amount of horses and oxen decreased by 50 %, and cats by 25 %). In return, the use of primates becomes more and more significant and is certainly not going to weak because of their scientific interests.

Concerning the study results, when significant differences were revealed between the 2001 and the 2004 figures, some verification were done in order to know what was the origin of these sudden evolutions. Each time these differences were explained by either new activity, for example the obtainment of therapeutic antibodies for rabbits increased by 74 %, or the closure of laboratories. They could be explained too by mistakes typed in the 2001 study report (concerning reptiles for example). The other variations are not significant and support the figures provided by experimental centres and laboratories.

This study allows estimating that public sector uses a third of the total amount of animals, of which 65 % is for basic research and education. On the other hand, private sector uses the remaining two third, of which 37 % are dedicated to research and development, 46 % to production and control, and 11 % to toxicological evaluations.

This study allows showing too that centres for animal experimentation are about 450 (it can vary depending on juridical conventions that link laboratories to these centres). It represents a third of the figure established in 1990. This decrease of the amount of experimental centres shows that henceforth laboratories are regrouped in order to dispose of centralized installations and competent staff. The « disappearance » of 900 experimental animal houses shows the pressure brought by the associations and the concerned authorities for fifteen years. It was engendered by very significant investments to come up to the current sanitary, ethic and scientific expectances. Of course, this diminution did not obviously drive to a decrease of the amount of animals with the same proportion, but it set practices that assure respect and well-being to animals.

TABLE 1: NUMBER OF ANIMALS USED IN RELATION TO THEIR PLACE OF ORIGIN

Origin versus species

	1.1	1.2	1.3	1.4	1.5	1.6	1.7
	Species	Total	Animals coming from registered	Animals coming from	Animals coming from	Animals coming from	Re-used animals
			breeding or supplying	elsewhere in the EC	Member Countries of the	other origins	
			establishments within the reporting		Council of Europe which are		
			country		parties to the Convention ETS		
					123 (excluding EC Member		
					States)		
l.a.	Mice (Mus musculus)	1 510 334	1 409 076	21 809	2 383	77 066	
1.b.	Rats (Rattus norvegicus)	424 387	411 068	2 128	25	11 166	
1.c.	Guinea-Pigs (Cavia porcellus)	79 350	56 862	16 679	0	5 809	
1.d.	Hamsters (Mesocricetus)	8 691	7 672	75	0	944	
1.e.	Other Rodents (other Rodentia)	12 683					
1.f.	Rabbits (Oryctolagus cuniculus)	93 282	92 897	10	0	375	1 542
1.g.	Cats (Felis catus)	1 313	622	9	0	682	408
1.h.	Dogs (Canis familiaris)	5 539	3 662	20	0	1 857	690
1.i.	Ferrets (Mustela putorius furo)	155	85	0	0	70	0
1.j.	Other Carnivores (other Carnivora)	0					
1.k.	Horses, donkeys and cross breds (Equidae)	223					
1.1.	Pigs (Sus)	6 587					
1.m.	Goats (Capra)	442					
1.n.	Sheep (Ovis)	4 992					
1.o.	Cattle (Bos)	1 296					
1.p.	Prosimians (<i>Prosimia</i>)	578	578	0	0	0	30
1.q.	New World Monkeys (Ceboidea)	433	340	20	13	60	96
1.r.	Old World Monkeys (Cercopithecoidea)	2 778	809	38	0	1 931	427
1.s.	Apes (Hominoidea)	0	0	0	0	0	0
1.t.	Other Mammals (other Mammalia)	0					
1.u.	Quail (Coturnix coturnix)	4 023	3 983	0	0	40	0
1.v.	Other birds (other <i>Aves</i>)	102 240					
1.w.	Reptiles (Reptilia)	0					
1.x.	Amphibians (Amphibia)	15 675					
1.y.	Fish (Pisces)	50 397					
1.z.	TOTAL	2 325 398					

Note 1: Column 1.5 concerns only those Member Countries of the Council of Europe which, at the beginning of the reporting period, are Parties to the Convention ETS 123. Thus an updated list of those countries has to be used when filling in this column.

Note 2: Only the white boxes need to be completed.

Note 3: The number of re-used animals in column 1.7 should be excluded from the total in the column 1.2

TABLE 2: NUMBER OF ANIMALS USED IN EXPERIMENTS FOR SELECTED PURPOSES

Purpose versus species

	2.1	2.2	2.3	2.4	2.5	2.6	2.7	2.8	2.9	2.10
	Species	Biological	Research and	Production and	Production and	Toxicological	Diagnosis of	Education and	Other	Total
	•	studies of a	development of	quality control of	quality control of	and other safety	disease	training		
		fundamenta	products and	products and	products and	evaluations				
		1 nature	devices for human	devices for	devices for	(including				
			medicine and	human medicine	veterinary	safety				
			dentistry and for	and dentistry	medicine	evaluation of				
			veterinary			products and				
			medicine			devices for				
			(excluding			human				
			toxicological and			medicine and				
			other safety evaluations			dentistry and for veterinary				
			counted in column			medicine)				
			2.6)			medicine)				
2.a.	Mice	351 428	404 603	475 247	59 199	71 036	66 658	41 988	40 175	1 510 334
2.b.	Rats	73 253	205 258	19 913	14 031	69 933	497	15 714	25 788	424 387
2.c.	Guinea-Pigs	1 404	6 127	50 991	6 373	13 122	7	417	909	79 350
2.d.	Hamsters	2 043	3 320	151	2 103	144	910	12	8	8 691
2.e.	Other Rodents	745	10 645	0	0	0	27	0	1 266	12 683
2.f.	Rabbits	1 246	9 686	61 349	3 334	10 328	1 123	1 689	4 527	93 282
2.g.	Cats	53	396	0	458	24	0	9	373	1 313
2.h.	Dogs	106	1 062	148	491	3 427	0	32	273	5 539
2.i.	Ferrets	30	55	29	0	41	0	0	0	155
2.j.	Other Carnivores	0	0	0	0	0	0	0	0	0
2.k.	Horses, donkeys and cross	0	21	87	8	0	0	91	16	223
	breds									
2.1.	Pigs	159	2 421	4	1 407	1 002	1	350	1 243	6 587
2.m.	Goats	26	106	77	0	10	0	23	200	442
2.n.	Sheep	731	936	3 062	0	10	26	111	116	4 992
2.o.	Cattle	56	461	1	11	92	20	141	514	1 296
2.p.	Prosimians	382	0	0	0	0	0	0	196	578
2.q.	New World Monkeys	24	121	35	0	168	0	5	80	433
2.r.	Old World Monkeys	238	216	326	0	1 874	0	29	95	2 778
2.s.	Apes	0	0	0	0	0	0	0	0	0
2.t.	Other Mammals	0	0	0	0	0	0	0	0	0
2.u.	Quail	20	0	0	0	0	0	100	3 903	4 023
2.v.	Other birds	3 768	10 718	10 857	37 069	36 332	435	1 209	1 852	102 240
2.w.	Reptiles	0	0	0	0	0	0	0	0	0
2.x.	Amphibians	4 760	53	0	0	500	0	9 362	1 000	15 675
2.y.	Fish	41 140	0	0	0	4 948	0	1 439	2 870	50 397
2.z.	TOTAL	481 612	656 205	622 277	124 484	212 991	69 704	72 721	85 404	2 325 398

TABLE 3: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS

Products versus species

	3.1	3.2	3.3	3.4	3.5	3.6	3.7	3.8	3.9	3.10	3.11
	Species	Products/	Products/	Products/	Products/	Products/	Products/	Products/	Potential or	Other toxico-	Total
	1	substances or	substances	substances	substances	substances	substances	substances	actual contami-	logical or	
		devices for	used or	used or	used or	used or	used or	used or	nents in the	safety	
		human	intended to	intended to	intended to	intended to	intended to be	intended to be	general envi-	evaluations	
		medicine and	be used	be used	be used	be used	used mainly	used mainly	ronment which		
		dentistry and	mainly in	mainly in	mainly in	mainly as	as additives in	as additives in	do not appear in		
		for veterinary	agriculture	industry	the	cosmetics	food for	food for	other columns		
		medicine			household	or toiletries	human	animal			
							consumption	consumption			
3.a.	Mice	39 549	7 321	5 868	0	1 797	516	123	2 438	13 424	71 036
3.b.	Rats	44 318	3 177	5 693	16	2 226	229	0	1 565	12 709	69 933
3.c.	Guinea-Pigs	4 353	445	3 832	177	940	27	0	0	3 348	13 122
3.d.	Hamsters	142	0	2	0	0	0	0	0	0	144
3.e.	Other Rodents	0	0	0	0	0	0	0	0	0	0
3.f.	Rabbits	4 796	696	1 319	106	533	0	0	0	2 878	10 328
3.g.	Cats	24	0	0	0	0	0	0	0	0	24
3.h.	Dogs	2 623	134	108	0	0	0	0	0	562	3 427
3.i.	Ferrets	41	0	0	0	0	0	0	0	0	41
3.j.	Other Carnivores	0	0	0	0	0	0	0	0	0	0
3.k.	Horses, donkeys and cross breds	0	0	0	0	0	0	0	0	0	0
3.1.	Pigs	303	0	39	0	0	0	444	83	133	1 002
3.m.	Goats	0	0	0	0	0	0	0	10	0	10
3.n.	Sheep	0	0	0	0	0	0	10	0	0	10
3.0.	Cattle	67	0	0	0	0	0	25	0	0	92
3.p.	Prosimians	0	0	0	0	0	0	0	0	0	0
3.q.	New World Monkeys	168	0	0	0	0	0	0	0	0	168
3.r.	Old World Monkeys	970	0	6	0	0	0	0	0	898	1 874
3.s.	Apes	0	0	0	0	0	0	0	0	0	0
3.t.	Other Mammals	0	0	0	0	0	0	0	0	0	0
3.u.	Quail	0	0	0	0	0	0	0	0	0	0
3.v.	Other birds	262	0	98	0	0	0	30 519	366	5 087	36 332
3.w.	Reptiles	0	0	0	0	0	0	0	0	0	0
3.x.	Amphibians	0	400	0	0	0	0	100	0	0	500
3.y.	Fish	0	2 848	2 000	0	0	0	0	100	0	4 948
3.z.	TOTAL	97 616	15 021	18 965	299	5 496	772	31 221	4 562	39 039	212 991

TABLE 4: NUMBER OF ANIMALS USED IN EXPERIMENTS FOR STUDIES ON HUMAN AND ANIMAL DISEASES

Main categories versus species

	4.1	4.2	4.3	4.4	4.5	4.6	4.7
	Species	Human cardiovascular	Human nervous and	Human cancer (excluding	Other human diseases	Studies specific to animal	Total
		diseases	mental disorders	evaluations of carcinogenic		diseases	
				hazards or risks)			
4.a.	Mice	69 470	226 646	154 806	307 007	64 760	822 689
4.b.	Rats	47 369	112 450	17 732	99 236	2 221	279 008
4.c.	Guinea-Pigs	1 719	924	149	2 980	1 766	7 538
4.d.	Hamsters	1 078	1 117	0	2 031	2 047	6 273
4.e.	Other Rodents	0	10 633	0	114	670	11 417
4.f.	Rabbits	3 349	0	93	4 504	4 109	12 055
4.g.	Cats	0	14	0	127	308	449
4.h.	Dogs	130	36	11	654	337	1 168
4.i.	Ferrets	0	0	0	85	0	85
4.j.	Other Carnivores	0	0	0	0	0	0
4.k.	Horses, donkeys and cross breds	0	0	0	0	21	21
4.1.	Pigs	830	1	6	245	1 499	2 581
4.m.	Goats	9	0	0	1	122	132
4.n.	Sheep	152	40	0	116	1 385	1 693
4.o.	Cattle	1	0	0	0	536	537
4.p.	Prosimians	0	382	0	0	0	382
4.q.	New World Monkeys	9	29	0	107	0	145
4.r.	Old World Monkeys	9	69	52	315	9	454
4.s.	Apes	0	0	0	0	0	0
4.t.	Other Mammals	0	0	0	0	0	0
4.u.	Quail	0	0	0	20	0	20
4.v.	Other birds	5	0	0	0	14 916	14 921
4.w.	Reptiles	0	0	0	0	0	0
4.x.	Amphibians	0	649	2 018	1 869	277	4 813
4.y.	Fish	0	0	0	32 809	8 331	41 140
4.z.	TOTAL	124 130	352 990	174 867	452 220	103 314	1 207 521

TABLE 5: NUMBER OF ANIMALS USED IN PRODUCTION AND QUALITY CONTROL OF PRODUCTS AND DEVICES FOR HUMAN MEDICINE AND DENTISTRY AND FOR VETERINARY MEDICINE

	5.1	5.2	5.3	5.4	5.5	5.6	5.7	5.8
	Species	National legislation	EC legislation	Member Country of Council	Other legislation	Any combination of	No regulatory	Total
	-	specific to a single EC	including European	of Europe (but not EC)		5.2/ 5.3/ 5.4/ 5.5	requirements	
		Member State	Pharmacopoeia	legislation				
		1)	(requirements)	2)				
5.a.	Mice	5 219	92 021	0	500	428 624	8 082	534 446
5.b.	Rats	4 608	13 371	0	14 938	1 027	0	33 944
5.c.	Guinea-Pigs	0	9 411	0	0	47 947	6	57 364
5.d.	Hamsters	0	2 254	0	0	0	0	2 254
5.e.	Other Rodents	0	0	0	0	0	0	0
5.f.	Rabbits	6	7 978	0	0	56 680	19	64 683
5.g.	Cats	0	458	0	0	0	0	458
5.h.	Dogs	0	639	0	0	0	0	639
5.i.	Ferrets	0	23	0	0	6	0	29
5.j.	Other Carnivores	0	0	0	0	0	0	0
5.k.	Horses, donkeys and cross breds	0	0	0	0	95	0	95
5.1.	Pigs	0	1 342	0	0	4	65	1 411
5.m.	Goats	0	0	0	0	77	0	77
5.n.	Sheep	0	0	0	0	3 062	0	3 062
5.o.	Cattle	0	11	0	0	1	0	12
5.p.	Prosimians	0	0	0	0	0	0	0
5.q.	New World Monkeys	0	35	0	0	0	0	35
5.r.	Old World Monkeys	0	6	0	0	320	0	326
5.s.	Apes	0	0	0	0	0	0	0
5.t.	Other Mammals	0	0	0	0	0	0	0
5.u.	Quail	0	0	0	0	0	0	0
5.v.	Other birds	0	37 117	152	0	10 657	0	47 926
5.w.	Reptiles	0	0	0	0	0	0	0
5.x.	Amphibians	0	0	0	0	0	0	0
5.y.	Fish	0	0	0	0	0	0	0
5.z.	TOTAL	9 833	164 666	152	15 438	548 500	8 172	746 761

Examples:

5.2 – France is testing due to a UK (or FR) specific requirement

5.3 - UK is testing according to EC legislation

5.4 – Spain is testing due to a Hungarian requirement

5.5 – Sweden is testing due to a US specific requirement

5.6 - Germany is testing due to a Czech requirement (also an EC

requirement)

Note:

columns 5.2 - 5.5 refer to the legislation imposing that the test be carried out and not to the body which has issued the actual test method, guideline or protocol.

Example: a test required by French legislation and carried out in Belgium according to an

ISO protocol must be coded as a national (FR) legislative requirement and be

entered into column 5.2 in the tables submitted by Belgium.

Footnotes: 1) EC Member States: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden, United Kingdom

2) Member Countries of Council of Europe (non-EC): Albania, Andorra, Bulgaria, Croatia, Cyprus, Czech Rep., Estonia, Hungary, Iceland, Latvia, Liechtenstein, Lithuania, Malta, Moldova, Norway, Poland, Romania, Russia, San Marino, Slovakia, Slovenia, Switzerland, 'the former Yugoslav Rep. of Macedonia', Turkey, Ukraine

TABLE 6: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS

	6.1	6.2	6.3	6.4	6.5	6.6	6.7	6.8
	Species	National legislation	EC legislation	Member Country of Council	Other legislation	Any combination of	No regulatory	Total
		specific to a single EC	including European	of Europe (but not EC)		6.2/ 6.3/ 6.4/ 6.5	requirements	
		Member State	Pharmacopoeia	legislation				
		1)	(requirements)	2)				
6.a.	Mice	7 381	17 787	22	3 586	34 457	7 803	71 036
6.b.	Rats	568	8 729	0	5 966	48 339	6 331	69 933
6.c.	Guinea-Pigs	414	9 751	0	323	2 107	527	13 122
6.d.	Hamsters	0	78	0	0	64	2	144
6.e.	Other Rodents	0	0	0	0	0	0	0
6.f.	Rabbits	502	1 631	0	1 726	4 669	1 800	10 328
6.g.	Cats	0	24	0	0	0	0	24
6.h.	Dogs	0	231	0	510	2 547	139	3 427
6.i.	Ferrets	0	0	0	0	41	0	41
6.j.	Other Carnivores	0	0	0	0	0	0	0
6.k.	Horses, donkeys and cross breds	0	0	0	0	0	0	0
6.1.	Pigs	31	187	0	132	512	140	1 002
6.m.	Goats	0	0	0	0	0	10	10
6.n.	Sheep	0	0	0	0	10	0	10
6.0.	Cattle	0	67	0	0	25	0	92
6.p.	Prosimians	0	0	0	0	0	0	0
6.q.	New World Monkeys	0	0	0	0	168	0	168
6.r.	Old World Monkeys	0	253	0	488	1 035	98	1 874
6.s.	Apes	0	0	0	0	0	0	0
6.t.	Other Mammals	0	0	0	0	0	0	0
6.u.	Quail	0	0	0	0	0	0	0
6.v.	Other birds	629	98	0	0	35 605	0	36 332
6.w.	Reptiles	0	0	0	0	0	0	0
6.x.	Amphibians	500	0	0	0	0	0	500
6.y.	Fish	0	3 000	0	0	33	1 915	4 948
6.z.	TOTAL	10 025	41 836	22	12 731	129 612	18 765	212 991

Examples:

Footnotes:

6.2 – France is testing due to a UK (or FR) specific requirement

6.3 - UK is testing according to EC legislation

6.4 – Spain is testing due to a Hungarian requirement

6.5 – Sweden is testing due to a US specific requirement

6.6 - Germany is testing due to a Czech requirement (also an EC

requirement)

Note:

columns 6.2 - 6.5 refer to the legislation imposing that the test be carried out and not to the body which has issued the actual test method, guideline or protocol.

Example: a test required by French legislation and carried out in Belgium according to an

ISO protocol must be coded as a national (FR) legislative requirement and be

entered into column 6.2 in the tables submitted by Belgium.

1) EC Member States: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden, United Kingdom

2) Member Countries of Council of Europe (non-EC): Albania, Andorra, Bulgaria, Croatia, Cyprus, Czech Rep., Estonia, Hungary, Iceland, Latvia, Liechtenstein, Lithuania, Malta, Moldova, Norway, Poland, Romania, Russia, San Marino, Slovakia, Slovenia, Switzerland, 'the former Yugoslav Rep. of Macedonia', Turkey, Ukraine

TABLE 7: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS

Types of tests versus species

	7.1		7.2		7.3	7.4	7.5	7.6	7.7	7.8	7.9	7.10	7.11	7.12	7.13
	Species		ub-acute toxicity to (including limit to		Skin irritation	Skin sensitisatio	Eye irritation	Sub- chronic and	Carcino- genicity	Develop- mental	Muta- genicit	Repro- ductive	Toxicity to aquatic	Other	Total
			(including innit to	cst)	mmation	n	iiiitatioii	chronic	gemeny	toxicity	y	toxicity	vertebra-		
								toxicity		,			tes not		
													included		
													in other columns		
		7.2.1.	7.2.2	7.2.3									Columns		
		LD50,	Other lethal	Non lethal											
		LC50	methods	clinical signs											
				methods											
7.a.	Mice	2 005	17 724	9 119	2 493	8 033	0	12 909	5 105	912	1 001	315	0	11 420	71 036
7.b.	Rats	1 881	8 642	5 955	0	0	142	20 645	6 386	5 301	4 573	6 247	0	10 161	69 933
7.c.	Guinea-Pigs	0	92	282	1 919	8 239	0	352	0	0	0	0	0	2 238	13 122
7.d.	Hamsters	0	64	0	0	0	0	2	0	0	0	0	0	78	144
7.e.	Other Rodents	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.f.	Rabbits Cats	0	15 0	1 289	1 494	0	1 647	1 026 0	0	2 544	0	1 254	0	1 059 24	10 328
7.g. 7.h.	Dogs	0	166	0 599	0	0	0	2 429	0	0	0	0	0	233	3 427
7.ii.	Ferrets	0	0	41	0	0	0	0	0	0	0	0	0	233	41
7.i.	Other Carnivores	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.k.	Horses, donkeys and cross	0	0	0	0	0	0	0	0	0	0	0	0	0	0
/ .K.	breds						· ·			O			Ĭ		"
7.1.	Pigs	0	49	0	0	0	0	262	0	89	0	0	0	602	1 002
7.m.	Goats	0	0	0	0	0	0	0	0	0	0	0	0	10	10
7.n.	Sheep	0	0	0	0	0	0	0	0	0	0	0	0	10	10
7.o.	Cattle	0	0	0	0	0	0	0	0	0	0	0	0	92	92
7.p.	Prosimians	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.q.	New World Monkeys	0	72	78	0	0	0	18	0	0	0	0	0	0	168
7.r.	Old World Monkeys	0	0	259	0	0	33	1 556	0	0	0	0	0	26	1 874
7.s.	Apes	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.t.	Other Mammals	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.u.	Quail	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.v.	Other birds	0	0	5 087	0	0	0	98	0	0	0	0	0	31 147	36 332
7.w.	Reptiles	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.x.	Amphibians	0	0	0	0	0	0	0	0	0	0	0	0	500	500
7.y.	Fish	1 178	0	1 000	0	0	0	2 170	0	0	0	0	500	100	4 948
7.z.	TOTAL	5 064	26 824	23 709	5 906	16 272	1 822	41 467	11 491	8 846	5 574	7 816	500	57 700	212 991

TABLE 8: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS

Types of tests versus products

	8.1 Products	Acute and sub-acute toxicity testing methods (including limit test) 8.2.1. 8.2.2 8.2.3 Non lethal clinical signs methods		8.3 Skin irritation	8.4 Skin sensitisatio n	8.5 Eye irritation	8.6 Sub- chronic and chronic toxicity	8.7 Carcino genicity	8.8 Develop- mental toxicity	8.9 Muta- genicit y	8.10 Reproductive toxicity	8.11 Toxicity to aquatic vertebra- tes not included in other columns	8.12 Other	8.13 Total	
8.a.	Products/substances or devices for human medicine and dentistry and for veterinary medicine	2 016	13 462	15 447	1 216	6 197	792	18 681	5 623	3 485	5 016	5 643	0	20 038	97 616
8.b.	Products/substances used or intended to be used mainly in agriculture	2 111	1 683	1 865	102	230	56	5 896	1 723	666	0	134	555	0	15 021
8.c.	Products/substances used or intended to be used mainly in industry	568	1 080	1 218	2 455	972	119	9 156	2 488	873	2	0	0	34	18 965
8.d.	Products/substances used or intended to be used mainly in the household	0	18	0	36	133	67	0	0	0	0	0	0	45	299
8.e.	Products/substances used or intended to be used mainly as cosmetics or toiletries	0	349	684	413	2 222	281	966	0	368	213	0	0	0	5 496
8.f.	Products/substances used or intended to be used mainly as additives in food for human consumption	0	0	123	0	19	0	467	0	0	8	0	0	155	772
8.g.	Products/substances used or intended to be used mainly as additives in food for animal consumption	0	0	185	0	0	0	0	24	0	0	0	0	31 012	31 221
8.h.	Potential or actual contaminants in the general environment which do not appear in other columns	0	1 289	287	0	0	0	1 350	0	0	0	592	0	1 044	4 562
8.i.	Other toxicological or safety evaluations	409	6 943	1 779	372	2 096	367	18 251	473	2 298	2 042	1 180	0	2 829	39 039
8.j.	TOTAL	5 104	24 824	21 588	4 594	11 869	1 682	54 767	10 331	7 690	7 281	7 549	555	55 157	212 991

HUNGARY

Statistical data submitted

The statistical data have been submitted by the Ministry of Agriculture and Rural Development.

Comments of the Hungarian authorities

2005 was the first year when Hungarian user establishments furnished data on the number of animals used for experimental and other scientific purposes in the harmonized eight table version of statistical reporting format. Furthermore, the data in this format were supplied on a voluntary basis. (The Hungarian law in force prescribes the use of the former 5-table version for statistical reporting.) This situation resulted in two consequences.

- 1. It is very difficult to compare the data of 2005 with those of the previous years when the former 5-table version had been in use.
- 2. The novelty and unfamiliarity of the tables and lack of sufficient guidance on the meaning of the new columns may have had a negative impact on the accuracy and coherence of data. (For example, in Tables 5 and 6 the non mutually exclusive classification of regulatory requirements may have corrupted the precision of the breakdown of the total figures.)

All the above circumstances warrant caution in interpreting the data.

Comments relating to the number of animals used

The total number of animals used for experimental and other scientific purposes in 2005 was 297.209 which represents 19% decrease compared to the same figure of 2004. (It is worth to note that the total number of animals had been relatively stable (365-377 thousand) in the period of 2001-2004). The decrease was 25% in the number of mice, 7% in case of rats, 28% for guinea-pigs, 66% in other rodents and 47% within birds. The number of used dogs and cats practically did not change. In contrast to the general decreasing tendency the use of fish more than doubled (+138%) while the number of rabbits increased by 9%.

Despite the considerable reduction in the number of rodents from year 2004 to year 2005 (~59.000 animals) this group kept its proportion (86.4%) within the total number of animals. Notable changes can be observed in the proportion of birds (a drop from 8.9% to 5.9%) and that of fish (an increase from 1.1% to 3%).

Due to the limiting conditions described above, however, it cannot be fairly judged whether these changes represent the beginning of a longer-term tendency or just reflect natural variation of the data.

When analysed by the purposes of the use of animals a slight increase can be observed in the fundamental biological research segment (3.7%) while the number of animals substantially decreased in education (51%), in diagnosis of disease and toxicological evaluations (32% each) and in the human and veterinary medicine field (21%) including research, development, production and quality control. However, in absolute numbers the latter decrease (48.671) accounts for more than two thirds of the total decrease (68.008).

Compared to 2004 the proportion of fundamental research in overall usage augmented from 21% to 27% while that of medicine related use decreased from 62% to 60%. Toxicological and safety investigations form the third largest part (10%) of animal usage.

TABLE 1: NUMBER OF ANIMALS USED IN RELATION TO THEIR PLACE OF ORIGIN

Origin versus species

	1.1	1.2	1.3	1.4	1.5	1.6	1.7
	Species	Total	Animals coming from registered	Animals coming from	Animals coming from	Animals coming from	Re-used animals
			breeding or supplying	elsewhere in the EC	Member Countries of the	other origins	
			establishments within the reporting		Council of Europe which are		
			country		parties to the Convention ETS		
					123 (excluding EC Member		
					States)		
1.a.	Mice (Mus musculus)	138312	106993	29067	0	2252	
1.b.	Rats (Rattus norvegicus)	109479	102798	6681	0	0	
1.c.	Guinea-Pigs (Cavia porcellus)	8360	4688	3672	0	0	
1.d.	Hamsters (Mesocricetus)	137	137	0	0	0	
1.e.	Other Rodents (other <i>Rodentia</i>)	381					
1.f.	Rabbits (Oryctolagus cuniculus)	9152	8640	0	0	512	0
1.g.	Cats (Felis catus)	124	121	0	0	3	0
1.h.	Dogs (Canis familiaris)	1206	966	104	0	136	0
1.i.	Ferrets (Mustela putorius furo)	0	0	0	0	0	0
1.j.	Other Carnivores (other Carnivora)	0					
1.k.	Horses, donkeys and cross breds (Equidae)	6					
1.1.	Pigs (Sus)	882					
1.m.	Goats (Capra)	2					
1.n.	Sheep (Ovis)	381					
1.o.	Cattle (Bos)	32					
1.p.	Prosimians (Prosimia)	0	0	0	0	0	0
1.q.	New World Monkeys (Ceboidea)	0	0	0	0	0	0
1.r.	Old World Monkeys (Cercopithecoidea)	6	3	0	0	3	0
1.s.	Apes (Hominoidea)	0	0	0	0	0	0
1.t.	Other Mammals (other Mammalia)	0					
1.u.	Quail (Coturnix coturnix)	283	93	0	0	190	
1.v.	Other birds (other Aves)	17151					
1.w.	Reptiles (Reptilia)	25					
1.x.	Amphibians (Amphibia)	1709					
1.y.	Fish (Pisces)	9581					
1.z.	TOTAL	297209					

Note 1: Column 1.5 concerns only those Member Countries of the Council of Europe which, at the beginning of the reporting period, are Parties to the Convention ETS 123. Thus an updated list of those countries has to be used when filling in this column.

Note 2: Only the white boxes need to be completed.

Note 3: The number of re-used animals in column 1.7 should be excluded from the total in the column 1.2

TABLE 2: NUMBER OF ANIMALS USED IN EXPERIMENTS FOR SELECTED PURPOSES
Purpose versus species

Turpose versus species												
	2.1	2.2	2.3	2.4	2.5	2.6	2.7	2.8	2.9	2.10		
	Species	Biological	Research and	Production and	Production and	Toxicological	Diagnosis of	Education and	Other	Total		
		studies of a	development of	quality control of	quality control of	and other safety	disease	training				
		fundamenta	products and	products and	products and	evaluations						
		l nature	devices for human	devices for	devices for	(including						
			medicine and	human medicine	veterinary	safety						
			dentistry and for	and dentistry	medicine	evaluation of						
			veterinary			products and						
			medicine			devices for						
			(excluding			human						
			toxicological and			medicine and						
			other safety			dentistry and						
			evaluations			for veterinary						
			counted in column			medicine)						
2 -	Miss	24050	2.6)	22717	0	0405	7050	000	20	420240		
2.a. 2.b.	Mice Rats	31950	67452 64523	22/1/	0	8125 7625	7050 0	988 1497	30	138312 109479		
		35834 771	2417	2562		2554			18			
2.c. 2.d.	Guinea-Pigs	137	2417	2562	0	2554	16 0	22 0	0	8360 137		
2.d. 2.e.	Hamsters Other Rodents		81	0			0	0		381		
		0			0	300		•	0			
2.f.	Rabbits Cats	1146 109	3995	3011	24	702	105	167 15	2 0	9152		
2.g.		273	0 92	0	0	0	0	208		124		
2.h.	Dogs			0	0	633	0		0	1206		
2.i.	Ferrets	0	0	0	0	0	0	0	0	0		
2.j.	Other Carnivores	0	0	0	0	0	0	0	0	0		
2.k.	Horses, donkeys and cross	0	0	0	0	0	0	6	0	6		
2.1.	breds Pigs	173	261	0	0	26	55	82	285	882		
2.n.	Goats	0	0	0	0	0	0	2	263	2		
		19	189		24		3	2	140	381		
2.n. 2.o.	Sheep Cattle	6	12	0	0	8	0	6	0	32		
	Prosimians	0	0	0	0	0	0	0	0	0		
2.p.							0					
2.q.	New World Monkeys	0	0	0	0	0		0	0	<u> </u>		
2.r.	Old World Monkeys	6		0	0	0	0					
2.s.	Apes	0	0	0	0	0	0	0	0	0		
2.t.	Other Mammals	0	0	0	0		0	0	0	•		
2.u.	Quail	93	0	0	0	190	0	0	0	283		
2.v.	Other birds	3068	8070	132	3165	2244	360	109	3	17151		
2.w.	Reptiles	25	0	0	0	0	0	0	0	25		
2.x.	Amphibians	458	0	0	0	0	0	1251	0	1709		
2.y.	Fish	5365	0	0	0	3330	0	386	500	9581		
2.z.	TOTAL	79433	147092	28422	3213	25741	7589	4741	978	297209		

TABLE 3: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS

Products versus species

	3.1	3.2	3.3	3.4	3.5	3.6	3.7	3.8	3.9	3.10	3.11
	Species	Products/	Products/	Products/	Products/	Products/	Products/	Products/	Potential or	Other toxico-	Total
		substances or	substances	substances	substances	substances	substances	substances	actual contami-	logical or	
		devices for	used or	used or	used or	used or	used or	used or	nents in the	safety	
		human	intended to	intended to	intended to	intended to	intended to be	intended to be	general envi-	evaluations	
		medicine and	be used	be used	be used	be used	used mainly	used mainly	ronment which		
		dentistry and	mainly in	mainly in	mainly in	mainly as	as additives in	as additives in	do not appear in		
		for veterinary	agriculture	industry	the	cosmetics	food for	food for	other columns		
		medicine			household	or toiletries	human	animal			
							consumption	consumption			
3.a.	Mice	2994	321	0	0	0	0	0	556	4254	8125
3.b.	Rats	1556	1317	13	0	0	52	0	394	4293	7625
3.c.	Guinea-Pigs	208	2	0	0	0	0	0	0	2344	2554
3.d.	Hamsters	0	0	0	0	0	0	0	0	0	0
3.e.	Other Rodents	300	0	0	0	0	0	0	0	0	300
3.f.	Rabbits	55	18	0	0	0	0	0	0	629	702
3.g.	Cats	0	0	0	0	0	0	0	0	0	0
3.h.	Dogs	296	0	0	0	0	0	0	0	337	633
3.i.	Ferrets	0	0	0	0	0	0	0	0	0	0
3.j.	Other Carnivores	0	0	0	0	0	0	0	0	0	0
3.k.	Horses, donkeys and cross breds	0	0	0	0	0	0	0	0	0	0
3.1.	Pigs	6	0	0	0	0	0	0	20	0	26
3.m.	Goats	0	0	0	0	0	0	0	0	0	0
3.n.	Sheep	4	0	0	0	0	0	0	0	0	4
3.o.	Cattle	8	0	0	0	0	0	0	0	0	8
3.p.	Prosimians	0	0	0	0	0	0	0	0	0	0
3.q.	New World Monkeys	0	0	0	0	0	0	0	0	0	0
3.r.	Old World Monkeys	0	0	0	0	0	0	0	0	0	0
3.s.	Apes	0	0	0	0	0	0	0	0	0	0
3.t.	Other Mammals	0	0	0	0	0	0	0	0	0	0
3.u.	Quail	0	190	0	0	0	0	0	0	0	190
3.v.	Other birds	1444	0	0	0	0	0	0	800	0	2244
3.w.	Reptiles	0	0	0	0	0	0	0	0	0	0
3.x.	Amphibians	0	0	0	0	0	0	0	0	0	0
3.y.	Fish	1000	430	0	0	0	0	0	1000	900	3330
3.z.	TOTAL	7871	2278	13	0	0	52	0	2770	12757	25741

TABLE 4: NUMBER OF ANIMALS USED IN EXPERIMENTS FOR STUDIES ON HUMAN AND ANIMAL DISEASES

Main categories versus species

	4.1	4.2	4.3	4.4	4.5	4.6	4.7
	Species	Human cardiovascular	Human nervous and	Human cancer (excluding	Other human diseases	Studies specific to animal	Total
		diseases	mental disorders	evaluations of carcinogenic		diseases	
				hazards or risks)			
4.a.	Mice	2146	55622	7607	13195	5982	84552
4.b.	Rats	3601	54589	1003	6056	15	65264
4.c.	Guinea-Pigs	59	93	0	2167	301	2620
4.d.	Hamsters	0	0	0	0	0	0
4.e.	Other Rodents	0	75	0	6	0	81
4.f.	Rabbits	350	2753	0	196	707	4006
4.g.	Cats	0	0	0	0	0	0
4.h.	Dogs	165	9	0	18	43	235
4.i.	Ferrets	0	0	0	0	0	0
4.j.	Other Carnivores	0	0	0	0	0	0
4.k.	Horses, donkeys and cross breds	0	0	0	0	0	0
4.1.	Pigs	61	0	0	14	189	264
4.m.	Goats	0	0	0	0	0	0
4.n.	Sheep	0	0	0	3	277	280
4.0.	Cattle	0	0	0	0	20	20
4.p.	Prosimians	0	0	0	0	0	0
4.q.	New World Monkeys	0	0	0	0	0	0
4.r.	Old World Monkeys	0	0	0	0	0	0
4.s.	Apes	0	0	0	0	0	0
4.t.	Other Mammals	0	0	0	0	0	0
4.u.	Quail	0	0	0	0	0	0
4.v.	Other birds	0	818	0	10	9906	10734
4.w.	Reptiles	0	0	0	0	0	0
4.x.	Amphibians	0	0	0	0	0	0
4.y.	Fish	0	0	0	0	300	300
4.z.	TOTAL	6382	113959	8610	21665	17740	168356

TABLE 5: NUMBER OF ANIMALS USED IN PRODUCTION AND QUALITY CONTROL OF PRODUCTS AND DEVICES FOR HUMAN MEDICINE AND DENTISTRY AND FOR VETERINARY MEDICINE

	5.1	5.2	5.3	5.4	5.5	5.6	5.7	5.8
	Species	National legislation	EC legislation	Member Country of Council	Other legislation	Any combination of	No regulatory	Total
		specific to a single EC	including European	of Europe (but not EC)		5.2/ 5.3/ 5.4/ 5.5	requirements	
		Member State	Pharmacopoeia	legislation				
		1)	(requirements)	2)				
5.a.	Mice	0	17952	0	0	4340	425	22717
5.b.	Rats	0	0	0	0	0	0	0
5.c.	Guinea-Pigs	0	1317	0	0	1157	88	2562
5.d.	Hamsters	0	0	0	0	0	0	0
5.e.	Other Rodents	0	0	0	0	0	0	0
5.f.	Rabbits	24	2981	0	0	30	0	3035
5.g.	Cats	0	0	0	0	0	0	0
5.h.	Dogs	0	0	0	0	0	0	0
5.i.	Ferrets	0	0	0	0	0	0	0
5.j.	Other Carnivores	0	0	0	0	0	0	0
5.k.	Horses, donkeys and cross breds	0	0	0	0	0	0	0
5.1.	Pigs	0	0	0	0	0	0	0
5.m.	Goats	0	0	0	0	0	0	0
5.n.	Sheep	24	0	0	0	0	0	24
5.o.	Cattle	0	0	0	0	0	0	0
5.p.	Prosimians	0	0	0	0	0	0	0
5.q.	New World Monkeys	0	0	0	0	0	0	0
5.r.	Old World Monkeys	0	0	0	0	0	0	0
5.s.	Apes	0	0	0	0	0	0	0
5.t.	Other Mammals	0	0	0	0	0	0	0
5.u.	Quail	0	0	0	0	0	0	0
5.v.	Other birds	100	3065	0	0	130	2	3297
5.w.	Reptiles	0	0	0	0	0	0	0
5.x.	Amphibians	0	0	0	0	0	0	0
5.y.	Fish	0	0	0	0	0	0	0
5.z.	TOTAL	148	25315	0	0	5657	515	31635

Examples:

5.2 – France is testing due to a UK (or FR) specific requirement

5.3 - UK is testing according to EC legislation

5.4 – Spain is testing due to a Hungarian requirement

5.5 – Sweden is testing due to a US specific requirement

5.6 - Germany is testing due to a Czech requirement (also an EC

requirement)

Note: columns 5.2 - 5.5 refer to the legislation imposing that the test be carried out and

not to the body which has issued the actual test method, guideline or protocol.

Example: a test required by French legislation and carried out in Belgium according to an

 $ISO\ protocol\ must\ be\ coded\ as\ a\ national\ (FR)\ legislative\ requirement\ and\ be$

entered into column 5.2 in the tables submitted by Belgium.

Footnotes:

1) EC Member States: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden, United Kingdom

2) Member Countries of Council of Europe (non-EC): Albania, Andorra, Bulgaria, Croatia, Cyprus, Czech Rep., Estonia, Hungary, Iceland, Latvia, Liechtenstein, Lithuania, Malta, Moldova, Norway, Poland, Romania, Russia, San Marino, Slovakia, Slovenia, Switzerland, 'the former Yugoslav Rep. of Macedonia', Turkey, Ukraine

TABLE 6: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS

	6.1	6.2	6.3	6.4	6.5	6.6	6.7	6.8
	Species	National legislation	EC legislation	Member Country of Council	Other legislation	Any combination of	No regulatory	Total
	•	specific to a single EC	including European	of Europe (but not EC)		6.2/ 6.3/ 6.4/ 6.5	requirements	
		Member State	Pharmacopoeia	legislation			•	
		1)	(requirements)	2)				
6.a.	Mice	2779	1839	148	0	3359	0	8125
6.b.	Rats	945	900	646	0	5121	13	7625
6.c.	Guinea-Pigs	0	946	0	0	1608	0	2554
6.d.	Hamsters	0	0	0	0	0	0	0
6.e.	Other Rodents	0	300	0	0	0	0	300
6.f.	Rabbits	6	76	0	0	620	0	702
6.g.	Cats	0	0	0	0	0	0	0
6.h.	Dogs	242	60	0	0	331	0	633
6.i.	Ferrets	0	0	0	0	0	0	0
6.j.	Other Carnivores	0	0	0	0	0	0	0
6.k.	Horses, donkeys and cross breds	0	0	0	0	0	0	0
6.1.	Pigs	0	6	0	0	0	20	26
6.m.	Goats	0	0	0	0	0	0	0
6.n.	Sheep	0	4	0	0	0	0	4
6.0.	Cattle	0	8	0	0	0	0	8
6.p.	Prosimians	0	0	0	0	0	0	0
6.q.	New World Monkeys	0	0	0	0	0	0	0
6.r.	Old World Monkeys	0	0	0	0	0	0	0
6.s.	Apes	0	0	0	0	0	0	0
6.t.	Other Mammals	0	0	0	0	0	0	0
6.u.	Quail	0	190	0	0	0	0	190
6.v.	Other birds	0	1182	0	0	0	1062	2244
6.w.	Reptiles	0	0	0	0	0	0	0
6.x.	Amphibians	0	0	0	0	0	0	0
6.y.	Fish	1000	1430	0	0	900	0	3330
6.z.	TOTAL	4972	6941	794	0	11939	1095	25741

Examples:

6.2 – France is testing due to a UK (or FR) specific requirement

6.3 - UK is testing according to EC legislation

6.4 – Spain is testing due to a Hungarian requirement

6.5 – Sweden is testing due to a US specific requirement

6.6 - Germany is testing due to a Czech requirement (also an EC requirement)

Note:

columns 6.2 - 6.5 refer to the legislation imposing that the test be carried out and

not to the body which has issued the actual test method, guideline or protocol.

a test required by French legislation and carried out in Belgium according to an ISO protocol must be coded as a national (FR) legislative requirement and be

entered into column 6.2 in the tables submitted by Belgium.

Footnotes:

1) EC Member States: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden, United Kingdom

2) Member Countries of Council of Europe (non-EC): Albania, Andorra, Bulgaria, Croatia, Cyprus, Czech Rep., Estonia, Hungary, Iceland, Latvia, Liechtenstein, Lithuania, Malta, Moldova, Norway, Poland, Romania, Russia, San Marino, Slovakia, Slovenia, Switzerland, 'the former Yugoslav Rep. of Macedonia', Turkey, Ukraine

TABLE 7: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS

Types of tests versus species

	7.1 Species	7.2 Acute and sub-acute toxicity testing methods (including limit test)			7.3 Skin	7.4 Skin	7.5 Eye	7.6 Sub-	7.7 Carcino-	7.8 Develop-	7.9 Muta-	7.10 Repro-	7.11 Toxicity	7.12 Other	7.13 Total
	Sp. 1.1.10				irritation	sensitisatio	irritation	chronic and	genicity	mental	genicit	ductive	to aquatic	0 11101	
						n		chronic		toxicity	у	toxicity	vertebra-		
								toxicity					tes not included		
													in other		
													columns		
		7.2.1.	7.2.2	7.2.3											
		LD50, LC50	Other lethal methods	Non lethal clinical signs											
		LC30	methods	methods											
7.a.	Mice	1781	427	2282	0	0	0	40	0	6	1068	0	0	2521	8125
7.b.	Rats	160	529	2915	0	0	0	1129	47	6	13	773	0	2053	7625
7.c.	Guinea-Pigs	368	0	419	0	1091	0	0	0	0	0	0	0	676	2554
7.d.	Hamsters	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.e.	Other Rodents	0	0	300	0	0	0	0	0	0	0	0	0	0	300
7.f.	Rabbits	0	0	64	143	0	111	0	0	0	0	252	0	132	702
7.g.	Cats	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.h.	Dogs	0	0	311	0	0	0	200	0	0	0	0	0	122	633
7.i.	Ferrets	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.j.	Other Carnivores	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.k.	Horses, donkeys and cross breds	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.1.	Pigs	0	0	6	0	0	0	0	0	0	0	0	0	20	26
7.m.	Goats	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.n.	Sheep	0	0	4	0	0	0	0	0	0	0	0	0	0	4
7.o.	Cattle	0	0	8	0	0	0	0	0	0	0	0	0	0	8
7.p.	Prosimians	0	0	0	0	0		0	0	0	0	0	0	0	0
7.q.	New World Monkeys	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.r.	Old World Monkeys	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.s.	Apes	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.t.	Other Mammals	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.u.	Quail	0	110	80	0	0	0	0	0	0	0	0	0	0	190
7.v.	Other birds	0	0	1008	0	0	0	0	0	0	0	0	0	1236	2244
7.w.	Reptiles	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.x.	Amphibians	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.y.	Fish	2330	0	900	0	0	0	0	0	100	0	0	0	0	3330
7.z.	TOTAL	4639	1066	8297	143	1091	111	1369	47	112	1081	1025	0	6760	25741

TABLE 8: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS

Types of tests versus products

	8.1 Products		8.2 nd sub-acute toxiods (including li		8.3 Skin irritation	8.4 Skin sensitisatio	8.5 Eye irritation	8.6 Sub- chronic	8.7 Carcino genicity	8.8 Develop- mental	8.9 Muta- genicit	8.10 Repro- ductive	8.11 Toxicity to aquatic	8.12 Other	8.13 Total
			, 0	,		n		and chronic toxicity		toxicity	у	toxicity	vertebra- tes not included in other columns		
		8.2.1. LD50, LC50	8.2.2 Other lethal methods	8.2.3 Non lethal clinical signs methods											
8.a.	Products/substances or devices for human medicine and dentistry and for veterinary medicine	2778	24	2924	9	0	0	0	0	100	0	0	0	2036	7871
8.b.	Products/substances used or intended to be used mainly in agriculture	490	110	1425	12	0	111	80	0	0	0	0	0	158	2386
8.c.	Products/substances used or intended to be used mainly in industry	0	0	0	0	0	0	0	0	0	13	0	0	0	13
8.d.	Products/substances used or intended to be used mainly in the household	0	0	0	0	0	0	0	0	0	0	0	0	0	0
8.e.	Products/substances used or intended to be used mainly as cosmetics or toiletries	0	0	0	0	0	0	0	0	0	0	0	0	0	0
8.f.	Products/substances used or intended to be used mainly as additives in food for human consumption	0	0	52	0	0	0	0	0	0	0	0	0	0	52
8.g.	Products/substances used or intended to be used mainly as additives in food for animal consumption	0	0	0	0	0	0	0	0	0	0	0	0	0	0
8.h.	Potential or actual contaminants in the general environment which do not appear in other columns	1000	0	760	0	0	0	0	47	12	0	131	0	820	2770
8.i.	Other toxicological or safety evaluations	371	932	3136	122	1091	0	1289	0	0	1068	894	0	3746	12649
8.j.	TOTAL	4639	1066	8297	143	1091	111	1369	47	112	1081	1025	0	6760	25741

IRELAND

Statistical data submitted

The statistical data for Ireland have been provided by the Department of Health and Children.

Comments of Irish authorities

General

- -A total of 37,940 animals were used. This represents a reduction of 27% compared to 2002 (the last published figures).
- There were 539 valid licences during the period 1 January 2005 31 December 2005.
- 171 new licences were issued in 2005. This is an increase of 13% compared to 2002.
- Rodents accounted for 67% of all animals used.
- No primates were used. This was in accordance with Ireland's policy not to licence for the use of primates.
- Of the animals used, 39% (14,779) were bred in registered breeding establishments in Ireland.
- Universities and Colleges accounted for 76% (28,904) of all animals used in scientific procedures.
- 58% of all procedures (21,929) used no anaesthesia (Certificate A). Certificate A is granted where the anaesthesia is considered to be more traumatic to the animal than the experiment itself or where anaesthesia is incompatible with the object of the experiment.
- 20% of animals (7,557) were used in procedures involving anaesthesia with permitted recovery (Certificate B).
- 3,336 genetically modified animals were used in experimental activity. This represents approximately 9% of the total numbers used.

Animals Used for Selected Purposes

- 9% of animals (3,472) were involved in studies specific to animal diseases.
- Of the 382 pigs used in 2005, 69% (263) were involved in studies on human and animal diseases.
- 119 cats were used, 64 of which were used in toxicology and other safety evaluations.
- 167 dogs were used, a reduction of 14% since 2002.
- Education and training accounted for 2% (688) of the animals used.
- Of the 2,024 other birds, 95% (1,914) were used in behavioural studies.

- 82% (313) of the rabbits used were for the study of human cardiovascular diseases.
- 189 horses were used, an increase of 170 since 2002. 91% of the horses used were for EC legislation including European Pharmacopoeia requirements. 117 of the horses were used with a Certificate A. Certificate A is granted where the anaesthesia is considered to be more traumatic to the animal than the experiment itself or where anaesthesia is incompatible with the object of the experiment.

Toxicological and other Safety Evaluations

- No animals were used in the testing of cosmetic products.
- Toxicological and other safety evaluations accounted for 18% (6,869) of animals used.
- 98% of the animals used in toxicological and other safety evaluations were mice.
- 875 mice were used in LD₅₀ and LC₅₀ testing, a reduction of 33% since 2002.

TABLE 1: NUMBER OF ANIMALS USED IN RELATION TO THEIR PLACE OF ORIGIN

Origin versus species

	1.1	1.2	1.3	1.4	1.5	1.6	1.7
	Species	Total	Animals coming from registered	Animals coming from	Animals coming from	Animals coming from	Re-used animals
			breeding or supplying	elsewhere in the EC	Member Countries of the	other origins	
			establishments within the reporting		Council of Europe which are		
			country		parties to the Convention ETS		
					123 (excluding EC Member		
			0.707		States)		
1.a.	Mice (Mus musculus)	17 776	8 767	8 532		477	
1.b.	Rats (Rattus norvegicus)	7 722	5 733	1 864	60	65	
1.c.	Guinea-Pigs (Cavia porcellus)	4	4				
1.d.	Hamsters (Mesocricetus)	0					
1.e.	Other Rodents (other Rodentia)	0					
1.f.	Rabbits (Oryctolagus cuniculus)	379	19	360			
1.g.	Cats (Felis catus)	119	119				60
1.h.	Dogs (Canis familiaris)	167	137	30			92
1.i.	Ferrets (Mustela putorius furo)	0					
1.j.	Other Carnivores (other Carnivora)	0					
1.k.	Horses, donkeys and cross breds (Equidae)	189					
1.1.	Pigs (Sus)	382					
1.m.	Goats (Capra)	0					
1.n.	Sheep (Ovis)	601					
1.o.	Cattle (Bos)	2 109					
1.p.	Prosimians (Prosimia)	0					
1.q.	New World Monkeys (Ceboidea)	0					
1.r.	Old World Monkeys (Cercopithecoidea)	0					
1.s.	Apes (Hominoidea)	0					
1.t.	Other Mammals (other Mammalia)	48					
1.u.	Quail (Coturnix coturnix)	0					
1.v.	Other birds (other <i>Aves</i>)	2024					
1.w.	Reptiles (Reptilia)	0					
1.x.	Amphibians (Amphibia)	0					
1.y.	Fish (Pisces)	6 420					
1.z.	TOTAL	37940					

Note 1: Column 1.5 concerns only those Member Countries of the Council of Europe which, at the beginning of the reporting period, are Parties to the Convention ETS 123. Thus an updated list of those countries has to be used when filling in this column.

Note 2: Only the white boxes need to be completed.

Note 3: The number of re-used animals in column 1.7 should be excluded from the total in the column 1.2

TABLE 2: NUMBER OF ANIMALS USED IN EXPERIMENTS FOR SELECTED PURPOSES
Purpose versus species

					Purpose vers					
	2.1	2.2	2.3	2.4	2.5	2.6	2.7	2.8	2.9	2.10
	Species	Biological	Research and	Production and	Production and	Toxicological	Diagnosis of	Education and	Other	Total
		studies of a	development of	quality control of	quality control of	and other safety	disease	training		
		fundamenta	products and	products and	products and	evaluations				
		l nature	devices for human	devices for	devices for	(including				
			medicine and	human medicine	veterinary	safety				
			dentistry and for	and dentistry	medicine	evaluation of				
			veterinary medicine			products and devices for				
			(excluding			human				
			toxicological and			medicine and				
			other safety			dentistry and				
			evaluations			for veterinary				
			counted in column			medicine)				
			2.6)							
2.a.	Mice	9 922	603			6703	158	15	375	17776
2.b.	Rats	6 367	1209				76	26	44	7722
2.c.	Guinea-Pigs		4							4
2.d.	Hamsters									0
2.e.	Other Rodents									0
2.f.	Rabbits	61	304						14	379
2.g.	Cats		10	45		64				119
2.h.	Dogs		38	42		87				167
2.i.	Ferrets									0
2.j.	Other Carnivores									0
2.k.	Horses, donkeys and cross				172			5	12	189
	breds									
2.1.	Pigs	130	123				10	99	20	382
2.m.	Goats									0
2.n.	Sheep	62	1		72		3	463		601
2.o.	Cattle	1417	15		329	15		20	313	2109
2.p.	Prosimians									0
2.q.	New World Monkeys									0
2.r.	Old World Monkeys									0
2.s.	Apes									0
2.t.	Other Mammals	4	44							48
2.u.	Quail									0
2.v.	Other birds		7				110	60	1847	2024
2.w.	Reptiles									0
2.x.	Amphibians									0
2.y.	Fish	6408							12	6420
2.z.	TOTAL	24371	2358	87	573	6869	357	688	2637	37940

TABLE 3: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS

Products versus species

	3.1	3.2	3.3	3.4	3.5	3.6	3.7	3.8	3.9	3.10	3.11
	Species	Products/	Products/	Products/	Products/	Products/	Products/	Products/	Potential or	Other toxico-	Total
		substances or	substances	substances	substances	substances	substances	substances	actual contami-	logical or	
		devices for	used or	used or	used or	used or	used or	used or	nents in the	safety	
		human	intended to	intended to	intended to	intended to	intended to be	intended to be	general envi-	evaluations	
		medicine and	be used	be used	be used	be used	used mainly	used mainly	ronment which		
		dentistry and	mainly in	mainly in	mainly in	mainly as	as additives in	as additives in	do not appear in		
		for veterinary	agriculture	industry	the	cosmetics	food for	food for	other columns		
		medicine			household	or toiletries	human	animal			
							consumption	consumption			
3.a.	Mice	150								6553	6703
3.b.	Rats										0
3.c.	Guinea-Pigs										0
3.d.	Hamsters										0
3.e.	Other Rodents										0
3.f.	Rabbits										0
3.g.	Cats	64									64
3.h.	Dogs	87									87
3.i.	Ferrets										0
3.j.	Other Carnivores										0
3.k.	Horses, donkeys and cross breds										0
3.1.	Pigs										0
3.m.	Goats										0
3.n.	Sheep										0
3.o.	Cattle	15									15
3.p.	Prosimians										0
3.q.	New World Monkeys										0
3.r.	Old World Monkeys										0
3.s.	Apes										0
3.t.	Other Mammals										0
											0
3.u.	Quail										
3.u. 3.v.	Quail Other birds										0
	`										0
3.v.	Other birds Reptiles										
3.v. 3.w.	Other birds										0

TABLE 4: NUMBER OF ANIMALS USED IN EXPERIMENTS FOR STUDIES ON HUMAN AND ANIMAL DISEASES

Main categories versus species

	4.1	4.2	4.3	4.4	4.5	4.6	4.7
	Species	Human cardiovascular	Human nervous and	Human cancer (excluding	Other human diseases	Studies specific to animal	Total
		diseases	mental disorders	evaluations of carcinogenic		diseases	
				hazards or risks)			
4.a.	Mice	675	1927	1155	6768	158	10683
4.b.	Rats	1386	5379		887		7652
4.c.	Guinea-Pigs		4				4
4.d.	Hamsters						0
4.e.	Other Rodents						0
4.f.	Rabbits	313	2		50		365
4.g.	Cats	10					10
4.h.	Dogs				38		38
4.i.	Ferrets						0
4.j.	Other Carnivores						0
4.k.	Horses, donkeys and cross breds						0
4.1.	Pigs	101			56	106	263
4.m.	Goats						0
4.n.	Sheep	1			38	27	66
4.o.	Cattle					1432	1432
4.p.	Prosimians						0
4.q.	New World Monkeys						0
4.r.	Old World Monkeys						0
4.s.	Apes						0
4.t.	Other Mammals	4				44	48
4.u.	Quail						0
4.v.	Other birds	7				110	117
4.w.	Reptiles				_		0
4.x.	Amphibians						0
4.y.	Fish		23		4790	1595	6408
4.z.	TOTAL	2497	7335	1155	12627	3472	27086

TABLE 5: NUMBER OF ANIMALS USED IN PRODUCTION AND QUALITY CONTROL OF PRODUCTS AND DEVICES FOR HUMAN MEDICINE AND DENTISTRY AND FOR VETERINARY MEDICINE

Regulatory requirements versus species

			riogulator,	requirements versu	b bpecies			
	5.1	5.2	5.3	5.4	5.5	5.6	5.7	5.8
	Species	National legislation	EC legislation	Member Country of Council	Other legislation	Any combination of	No regulatory	Total
	1	specific to a single EC	including European	of Europe (but not EC)		5.2/ 5.3/ 5.4/ 5.5	requirements	
		Member State	Pharmacopoeia	legislation			1	
		1)	(requirements)	2)				
5.a.	Mice							0
5.b.	Rats							0
5.c.	Guinea-Pigs							0
5.d.	Hamsters							0
5.e.	Other Rodents							0
5.f.	Rabbits							0
5.g.	Cats					45		45
5.h.	Dogs					42		42
5.i.	Ferrets							0
5.j.	Other Carnivores							0
5.k.	Horses, donkeys and cross breds		172					172
5.1.	Pigs							0
5.m.	Goats							0
5.n.	Sheep		72					72
5.0.	Cattle		286				43	329
5.p.	Prosimians							0
5.q.	New World Monkeys							0
5.r.	Old World Monkeys							0
5.s.	Apes							0
5.t.	Other Mammals							0
5.u.	Quail							0
5.v.	Other birds							0
5.w.	Reptiles						·	0
5.x.	Amphibians							0
5.y.	Fish						·	0
5.z.	TOTAL	0	530	0	0	87	43	660

Examples:

5.2 – France is testing due to a UK (or FR) specific requirement

5.3 - UK is testing according to EC legislation

5.4 – Spain is testing due to a Hungarian requirement

5.5 – Sweden is testing due to a US specific requirement

5.6 – Germany is testing due to a Czech requirement (also an EC requirement)

Note:

Example:

columns 5.2 - 5.5 refer to the legislation imposing that the test be carried out and not to the body which has issued the actual test method, guideline or protocol.

a test required by French legislation and carried out in Belgium according to an

ISO protocol must be coded as a national (FR) legislative requirement and be

entered into column 5.2 in the tables submitted by Belgium.

Footnotes:

- 1) EC Member States: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden, United Kingdom
- 2) Member Countries of Council of Europe (non-EC): Albania, Andorra, Bulgaria, Croatia, Cyprus, Czech Rep., Estonia, Hungary, Iceland, Latvia, Liechtenstein, Lithuania, Malta, Moldova, Norway, Poland, Romania, Russia, San Marino, Slovakia, Slovenia, Switzerland, 'the former Yugoslav Rep. of Macedonia', Turkey, Ukraine

NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS

Regulatory requirements versus species

	6.1	6.2	6.3	6.4	6.5	6.6	6.7	6.8
	Species	National legislation	EC legislation	Member Country of Council	Other legislation	Any combination of	No regulatory	Total
		specific to a single EC	including European	of Europe (but not EC)	_	6.2/ 6.3/ 6.4/ 6.5	requirements	
		Member State	Pharmacopoeia	legislation				
		1)	(requirements)	2)				
6.a.	Mice		5238			1465		6703
6.b.	Rats							0
6.c.	Guinea-Pigs							0
6.d.	Hamsters							0
6.e.	Other Rodents							0
6.f.	Rabbits							0
6.g.	Cats	64						64
6.h.	Dogs	87						87
6.i.	Ferrets							0
6.j.	Other Carnivores							0
6.k.	Horses, donkeys and cross breds							0
6.1.	Pigs							0
6.m.	Goats							0
6.n.	Sheep							0
6.0.	Cattle						15	15
6.p.	Prosimians							0
6.q.	New World Monkeys							0
6.r.	Old World Monkeys							0
6.s.	Apes							0
6.t.	Other Mammals							0
6.u.	Quail							0
6.v.	Other birds							0
6.w.	Reptiles							0
6.x.	Amphibians							0
6.y.	Fish							0
6.z.	TOTAL	151	5238	0	0	1465	15	6869

Examples:

6.2 – France is testing due to a UK (or FR) specific requirement

Note:

Example:

columns 6.2 - 6.5 refer to the legislation imposing that the test be carried out and

6.3 - UK is testing according to EC legislation 6.4 – Spain is testing due to a Hungarian requirement

not to the body which has issued the actual test method, guideline or protocol. a test required by French legislation and carried out in Belgium according to an

6.5 – Sweden is testing due to a US specific requirement

ISO protocol must be coded as a national (FR) legislative requirement and be

6.6 - Germany is testing due to a Czech requirement (also an EC requirement)

entered into column 6.2 in the tables submitted by Belgium.

Footnotes:

EC Member States: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden, United Kingdom

Member Countries of Council of Europe (non-EC): Albania, Andorra, Bulgaria, Croatia, Cyprus, Czech Rep., Estonia, Hungary, Iceland, Latvia, Liechtenstein, Lithuania, Malta, Moldova, Norway, Poland, Romania, Russia, San Marino, Slovakia, Slovenia, Switzerland, 'the former Yugoslav Rep. of Macedonia', Turkey, Ukraine

TABLE 7: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS

Types of tests versus species

	7.1 Species	Acute and su	7.2 ub-acute toxicity	testing methods	7.3 Skin	7.4 Skin	7.5 Eye	7.6 Sub-	7.7 Carcino-	7.8 Develop-	7.9 Muta-	7.10 Repro-	7.11 Toxicity	7.12 Other	7.13 Total
		((including limit to	est)	irritation	sensitisatio n	irritation	chronic and chronic toxicity	genicity	mental toxicity	genicit y	ductive toxicity	to aquatic vertebra- tes not included in other		
		7.2.1. LD50, LC50	7.2.2 Other lethal methods	7.2.3 Non lethal clinical signs methods									columns		
7.a.	Mice	875	4363					1465							6703
7.b.	Rats														0
7.c.	Guinea-Pigs														0
7.d.	Hamsters														0
7.e.	Other Rodents														0
7.f.	Rabbits														0
7.g.	Cats													64	64
7.h.	Dogs													87	87
7.i.	Ferrets														0
7.j.	Other Carnivores														0
7.k.	Horses, donkeys and cross breds														0
7.1.	Pigs														0
7.m.	Goats														0
7.n.	Sheep														0
7.o.	Cattle			15											15
7.p.	Prosimians														0
7.q.	New World Monkeys														0
7.r.	Old World Monkeys														0
7.s.	Apes														0
7.t.	Other Mammals														0
7.u.	Quail														0
7.v.	Other birds														0
7.w.	Reptiles					-		-							0
7.x.	Amphibians														0
7.y.	Fish														0
7.z.	TOTAL	875	4363	15	0	0	0	1465	0	0	0	0	0	151	6869

TABLE 8: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS

Types of tests versus products

	8.1 Products		8.2 and sub-acute toxi ods (including li		8.3 Skin irritation	8.4 Skin sensitisatio n	8.5 Eye irritation	8.6 Sub- chronic and chronic toxicity	8.7 Carcino genicity	8.8 Develop- mental toxicity	8.9 Muta- genicit y	8.10 Reproductive toxicity	8.11 Toxicity to aquatic vertebra- tes not included in other columns	8.12 Other	8.13 Total
		LD50, LC50	Other lethal methods	Non lethal clinical signs methods											
8.a.	Products/substances or devices for human medicine and dentistry and for veterinary medicine	875	4363	15									1465	151	6869
8.b.	Products/substances used or intended to be used mainly in agriculture														0
8.c.	Products/substances used or intended to be used mainly in industry														0
8.d.	Products/substances used or intended to be used mainly in the household														0
8.e.	Products/substances used or intended to be used mainly as cosmetics or toiletries														0
8.f.	Products/substances used or intended to be used mainly as additives in food for human consumption														0
8.g.	Products/substances used or intended to be used mainly as additives in food for animal consumption														0
8.h.	Potential or actual contaminants in the general environment which do not appear in other columns														0
8.i.	Other toxicological or safety evaluations														0
8.j.	TOTAL	875	4363	15	0	0	0	0	0	0	0	0	1465	151	6869

ITALY

Statistical data submitted

The statistical data have been submitted by the Ministry of Health – Department for public veterinary health food and animal safety, Directorate-General for animal health and veterinary medicines, Office X

Comments of Italian authorities

The collected data are entered in the "harmonised EU statistical tables" agreed by the competent national authorities of the EU in 1997.

They generally confirm the downward trend in the total number of animals used in experiments, which has remained below the one million mark since 1999.

93.61% of the animals used were rodents and rabbits.

The tables also include data on animals used for in vitro studies (euthanised to remove organs, tissues and cells).

44.08% of the animals were used in basic biological studies.

27.42% of the animals were used in the research and development of products and devices for human medicine, dentistry and veterinary medicine.

15.38% of the animals were used in the production and quality control of products and devices for human medicine, dentistry and veterinary medicine.

8.9% of the animals were used in toxicological studies.

4.22% of the animals were used for diagnosis of disease, education and other purposes.

98.67% of the animals were used to study human diseases, while 1.33% were used to study animal diseases

Article 24 of Directive 86/609/EEC has allowed tighter rules to be introduced into Italian law, particularly regarding the use of non-human primates, cats and dogs, as may be seen from Article 3(2) of Legislative Decree 116/92, which states that "with regard to non-human primates, cats and dogs, the authorisation stipulated by Article 8(1)(b) is also required."

Special attention was also paid to the use of horses in experiments.

All in all, this means that horses, non-human primates, cats and dogs together account for **0.17%** of all animals used.

Cats are used in experiments in Italy only in investigations of diseases affecting cats themselves. Since 2003 no animals have been used to test finished cosmetic products.

Signed:Prof. Sergio Papalia

Director, Office

TABLE 1: NUMBER OF ANIMALS USED IN RELATION TO THEIR PLACE OF ORIGIN

Origin versus species

1.1	1.2	1.3	1.4	1.5	1.6	1.7
Species	Total	Animals coming from registered	Animals coming from	Animals coming from	Animals coming from	Re-used animals
Spring.		breeding or supplying	elsewhere in the EC	Member Countries of the	other origins	
		establishments within the reporting	***************************************	Council of Europe which are		
		country		parties to the Convention ETS		
		j		123 (excluding EC Member		
				States)		
1.a. Mice (Mus musculus)	534614	516400	6073	97	12044	
1.b. Rats (Rattus norvegicus)	279774	276681	2758	4	331	
1.c. Guinea-Pigs (Cavia porcellus)	11533	6879	4613	15	26	
1.d. Hamsters (Mesocricetus)	1537	1473	0	0	64	
1.e. Other Rodents (other <i>Rodentia</i>)	2303			0	0	
1.f. Rabbits (Oryctolagus cuniculus)	9916	9842	74	0	0	351
1.g. Cats (Felis catus)	30	0	30	0	0	0
1.h. Dogs (Canis familiaris)	1064	601	0	93	370	68
1.i. Ferrets (Mustela putorius furo)	0	0	0	0	0	0
1.j. Other Carnivores (other <i>Carnivora</i>)	0					
1.k. Horses, donkeys and cross breds (<i>Equidae</i>)	63					
1.1. Pigs (<i>Sus</i>)	2579					
1.m. Goats (Capra)	20					
1.n. Sheep (Ovis)	584					
1.o. Cattle (Bos)	1174					
1.p. Prosimians (<i>Prosimia</i>)	0	0	0	0	0	0
1.q. New World Monkeys (Ceboidea)	17	12	5	0	0	87
1.r. Old World Monkeys (Cercopithecoidea)	395	7	343	3	42	85
1.s. Apes (Hominoidea)	0	0	0	0	0	0
1.t. Other Mammals (other <i>Mammalia</i>)	68				0	0
1.u. Quail (Coturnix coturnix)	0	0	0	0	0	0
1.v. Other birds (other <i>Aves</i>)	31697					
1.w. Reptiles (<i>Reptilia</i>)	378					
1.x. Amphibians (Amphibia)	4636					
1.y. Fish (<i>Pisces</i>)	14584					
1.z. TOTAL	896966					

Note 1: Column 1.5 concerns only those Member Countries of the Council of Europe which, at the beginning of the reporting period, are Parties to the Convention ETS 123. Thus an updated list of those countries has to be used when filling in this column.

Note 2: Only the white boxes need to be completed.

Note 3: The number of re-used animals in column 1.7 should be excluded from the total in the column 1.2

TABLE 2: NUMBER OF ANIMALS USED IN EXPERIMENTS FOR SELECTED PURPOSES

Purpose versus species

	2.1	2.2	2.3	2.4	2.5	2.6	2.7	2.8	2.9	2.10
	Species	Biological	Research and	Production and	Production and	Toxicological	Diagnosis of	Education and	Other	Total
		studies of a	development of	quality control of	quality control of	and other safety	disease	training		
		fundamenta	products and	products and	products and	evaluations				
		1 nature	devices for human	devices for	devices for	(including				
			medicine and	human medicine	veterinary	safety				
			dentistry and for	and dentistry	medicine	evaluation of				
			veterinary			products and				
			medicine			devices for				
			(excluding			human medicine and				
			toxicological and							
			other safety evaluations			dentistry and for veterinary				
			counted in column			medicine)				
			2.6)			medicine)				
2.a.	Mice	292138	146808	26561	4744	34518	24245	403	5197	534614
2.b.	Rats	79546	83690	81993	170	30818	1115	317	2125	279774
2.c.	Guinea-Pigs	1778	4040	3740	451	1444	53	15	12	11533
2.d.	Hamsters	1092	76	0	0	57	312	0	0	1537
2.e.	Other Rodents	400	1043	0	0	0	860	0	0	2303
2.f.	Rabbits	1766	1228	4195	855	1626	38	0	208	9916
2.g.	Cats	0	30	0	0	0	0	0	0	30
2.h.	Dogs	12	59	0	0	993	0	0	0	1064
2.i.	Ferrets	0	0	0	0	0	0	0	0	0
2.j.	Other Carnivores	0	0	0	0	0	0	0	0	0
2.k.	Horses, donkeys and cross	34	3	24	0	0	0	0	2	63
	breds									
2.1.	Pigs	758	405	18	71	333	0	249	745	2579
2.m.	Goats	13	4	0	0	0	1	0	2	20
2.n.	Sheep	187	257	51	75	14	0	0	0	584
2.o.	Cattle	1024	62	1	73	0	10	0	4	1174
2.p.	Prosimians	0	0	0	0	0	0	0	0	0
2.q.	New World Monkeys	9	8	0	0	0	0	0	0	17
2.r.	Old World Monkeys	20	11	37	0	327	0	0	0	395
2.s.	Apes	0	0	0	0	0	0	0	0	0
2.t.	Other Mammals	58	0	0	10	0	0	0	0	68
2.u.	Quail	0	0	0	0	0	0	0	0	0
2.v.	Other birds	6915	2519	15	14621	6102	3	0	1522	31697
2.w.	Reptiles	348	0	0	0	0	0	0	30	378
2.x.	Amphibians	4495	30	0	0	42	69	0	0	4636
2.y.	Fish	4820	5674	0	310	3520	0	0	260	14584
2.z.	TOTAL	395413	245947	116635	21380	79794	26706	984	10107	896966

TABLE 3: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS

Products versus species

	3.1	3.2	3.3	3.4	3.5	3.6	3.7	3.8	3.9	3.10	3.11
	Species	Products/	Products/	Products/	Products/	Products/	Products/	Products/	Potential or	Other toxico-	Total
		substances or	substances	substances	substances	substances	substances	substances	actual	logical or	
		devices for	used or	used or	used or	used or	used or	used or	contaminants in	safety	
		human	intended to	intended to	intended to	intended to	intended to be	intended to be	the general	evaluations	
		medicine and	be used	be used	be used	be used	used mainly	used mainly	environment		
		dentistry and	mainly in	mainly in	mainly in	mainly as	as additives in	as additives in	which do not		
		for veterinary	agriculture	industry	the	cosmetics	food for	food for	appear in other		
		medicine			household	or toiletries	human	animal	columns		
							consumption	consumption			
3.a.	Mice	12523	69	290	0	0	390	182	2782	18282	34518
3.b.	Rats	20550	288	2424	0	0	766	0	4830	1960	30818
3.c.	Guinea-Pigs	959	70	397	0	0	0	0	0	18	1444
3.d.	Hamsters	57	0	0	0	0	0	0	0	0	57
3.e.	Other Rodents	0	0	0	0	0	0	0	0	0	0
3.f.	Rabbits	1479	0	129	0	0	0	0	0	18	1626
3.g.	Cats	0	0	0	0	0	0	0	0	0	0
3.h.	Dogs	929	0	64	0	0	0	0	0	0	993
3.i.	Ferrets	0	0	0	0	0	0	0	0	0	0
3.j.	Other Carnivores	0	0	0	0	0	0	0	0	0	0
3.k.	Horses, donkeys and cross breds	0	0	0	0	0	0	0	0	0	0
3.1.	Pigs	313	0	0	0	0	0	0	0	20	333
3.m.	Goats	0	0	0	0	0	0	0	0	0	0
3.n.	Sheep	12	0	0	0	0	0	0	0	2	14
3.0.	Cattle	0	0	0	0	0	0	0	0	0	0
3.p.	Prosimians	0	0	0	0	0	0	0	0	0	0
3.q.	New World Monkeys	0	0	0	0	0	0	0	0	0	0
3.r.	Old World Monkeys	327	0	0	0	0	0	0	0	0	327
3.s.	Apes	0	0	0	0	0	0	0	0	0	0
3.t.	Other Mammals	0	0	0	0	0	0	0	0	0	0
3.u.	Quail	0	0	0	0	0	0	0	0	0	0
3.v.	Other birds	6082	0	0	0	0	0	0	0	20	6102
3.w.	Reptiles	0	0	0	0	0	0	0	0	0	0
3.x.	Amphibians	0	0	0	0	0	0	0	0	42	42
3.y.	Fish	255	0	0	0	0	0	0	3265	0	3520
3.z.	TOTAL	43486	427	3304	0	0	1156	182	10877	20362	79794

TABLE 4: NUMBER OF ANIMALS USED IN EXPERIMENTS FOR STUDIES ON HUMAN AND ANIMAL DISEASES

Main categories versus species

	4.1	4.2	4.3	4.4	4.5	4.6	4.7
	Species	Human cardiovascular	Human nervous and	Human cancer (excluding	Other human diseases	Studies specific to animal	Total
		diseases	mental disorders	evaluations of carcinogenic		diseases	
				hazards or risks)			
4.a.	Mice	13061	61492	113322	132766	4449	325090
4.b.	Rats	7290	49905	9863	37583	196	104837
4.c.	Guinea-Pigs	632	966	0	2891	189	4678
4.d.	Hamsters	100	659	144	12	6	921
4.e.	Other Rodents	0	986	0	196	727	1909
4.f.	Rabbits	378	195	19	1030	120	1742
4.g.	Cats	0	0	0	0	30	30
4.h.	Dogs	6	141	268	49	6	470
4.i.	Ferrets	0	0	0	0	0	0
4.j.	Other Carnivores	0	0	0	0	0	0
4.k.	Horses, donkeys and cross breds	0	0	0	0	0	0
4.1.	Pigs	165	2	0	103	25	295
4.m.	Goats	0	0	0	0	0	0
4.n.	Sheep	11	0	40	18	32	101
4.0.	Cattle	0	0	0	7	0	7
4.p.	Prosimians	0	0	0	0	0	0
4.q.	New World Monkeys	0	12	0	0	0	12
4.r.	Old World Monkeys	0	3	125	6	0	134
4.s.	Apes	0	0	0	0	0	0
4.t.	Other Mammals	0	0	0	0	0	0
4.u.	Quail	0	0	0	0	0	0
4.v.	Other birds	0	0	0	22	70	92
4.w.	Reptiles	0	0	0	0	0	0
4.x.	Amphibians	0	131	0	451	0	582
4.y.	Fish	0	0	221	0	0	221
4.z.	TOTAL	21643	114492	124002	175134	5850	441121

TABLE 5: NUMBER OF ANIMALS USED IN PRODUCTION AND QUALITY CONTROL OF PRODUCTS AND DEVICES FOR HUMAN MEDICINE AND DENTISTRY AND FOR VETERINARY MEDICINE

Regulatory requirements versus species

	5.1	5.2	5.3	5.4	5.5	5.6	5.7	5.8
	Species	National legislation	EC legislation	Member Country of Council	Other legislation	Any combination of	No regulatory	Total
		specific to a single EC	including European	of Europe (but not EC)		5.2/ 5.3/ 5.4/ 5.5	requirements	
		Member State	Pharmacopoeia	legislation				
		1)	(requirements)	2)				
5.a.	Mice	4176	7816	0	40	15405	3868	31305
5.b.	Rats	425	1789	0	0	78237	1712	82163
5.c.	Guinea-Pigs	1326	29	0	0	2630	206	4191
5.d.	Hamsters	0	0	0	0	0	0	0
5.e.	Other Rodents	0	0	0	0	0	0	0
5.f.	Rabbits	1112	3297	0	0	460	181	5050
5.g.	Cats	0	0	0	0	0	0	0
5.h.	Dogs	0	0	0	0	0	0	0
5.i.	Ferrets	0	0	0	0	0	0	0
5.j.	Other Carnivores	0	0	0	0	0	0	0
5.k.	Horses, donkeys and cross breds	24	0	0	0	0	0	24
5.1.	Pigs	50	39	0	0	0	0	89
5.m.	Goats	0	0	0	0	0	0	0
5.n.	Sheep	119	7	0	0	0	0	126
5.o.	Cattle	57	17	0	0	0	0	74
5.p.	Prosimians	0	0	0	0	0	0	0
5.q.	New World Monkeys	0	0	0	0	0	0	0
5.r.	Old World Monkeys	0	0	0	0	37	0	37
5.s.	Apes	0	0	0	0	0	0	0
5.t.	Other Mammals	10	0	0	0	0	0	10
5.u.	Quail	0	0	0	0	0	0	0
5.v.	Other birds	1607	13029	0	0	0	0	14636
5.w.	Reptiles	0	0	0	0	0	0	0
5.x.	Amphibians	0	0	0	0	0	0	0
5.y.	Fish	0	0	0	0	0	310	310
5.z.	TOTAL	8906	26023	0	40	96769	6277	138015

Examples:

5.2 – France is testing due to a UK (or FR) specific requirement

5.3 - UK is testing according to EC legislation

5.4 – Spain is testing due to a Hungarian requirement

5.5 – Sweden is testing due to a US specific requirement

5.6 - Germany is testing due to a Czech requirement (also an EC

requirement)

Note:

columns 5.2 - 5.5 refer to the legislation imposing that the test be carried out and

not to the body which has issued the actual test method, guideline or protocol. a test required by French legislation and carried out in Belgium according to an

Example: ISO protocol must be coded as a national (FR) legislative requirement and be

entered into column 5.2 in the tables submitted by Belgium.

Footnotes:

EC Member States: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden, United Kingdom

Member Countries of Council of Europe (non-EC): Albania, Andorra, Bulgaria, Croatia, Cyprus, Czech Rep., Estonia, Hungary, Iceland, Latvia, Liechtenstein, Lithuania, Malta, Moldova, Norway, Poland, Romania, Russia, San Marino, Slovakia, Slovenia, Switzerland, 'the former Yugoslav Rep. of Macedonia', Turkey, Ukraine

NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS TABLE 6:

Regulatory requirements versus species

	6.1	6.2	6.3	6.4	6.5	6.6	6.7	6.8
	Species	National legislation	EC legislation	Member Country of Council	Other legislation	Any combination of	No regulatory	Total
	•	specific to a single EC	including European	of Europe (but not EC)	Č	6.2/ 6.3/ 6.4/ 6.5	requirements	
		Member State	Pharmacopoeia	legislation			•	
		1)	(requirements)	2)				
6.a.	Mice	23592	6728	0	390	3259	549	34518
6.b.	Rats	8821	8374	0	941	12359	323	30818
6.c.	Guinea-Pigs	199	491	0	0	754	0	1444
6.d.	Hamsters	0	48	0	0	9	0	57
6.e.	Other Rodents	0	0	0	0	0	0	0
6.f.	Rabbits	110	555	0	0	874	87	1626
6.g.	Cats	0	0	0	0	0	0	0
6.h.	Dogs	137	272	0	0	584	0	993
6.i.	Ferrets	0	0	0	0	0	0	0
6.j.	Other Carnivores	0	0	0	0	0	0	0
6.k.	Horses, donkeys and cross breds	0	0	0	0	0	0	0
6.1.	Pigs	20	313	0	0	0	0	333
6.m.	Goats	0	0	0	0	0	0	0
6.n.	Sheep	2	12	0	0	0	0	14
6.0.	Cattle	0	0	0	0	0	0	0
6.p.	Prosimians	0	0	0	0	0	0	0
6.q.	New World Monkeys	0	0	0	0	0	0	0
6.r.	Old World Monkeys	0	0	0	0	327	0	327
6.s.	Apes	0	0	0	0	0	0	0
6.t.	Other Mammals	0	0	0	0	0	0	0
6.u.	Quail	0	0	0	0	0	0	0
6.v.	Other birds	4840	1262	0	0	0	0	6102
6.w.	Reptiles	0	0	0	0	0	0	0
6.x.	Amphibians	42	0	0	0	0	0	42
6.y.	Fish	3450	0	0	0	0	70	3520
6.z.	TOTAL	41213	18055	0	1331	18166	1029	79794

Examples:

6.2 – France is testing due to a UK (or FR) specific requirement

6.3 - UK is testing according to EC legislation

6.4 – Spain is testing due to a Hungarian requirement

6.5 – Sweden is testing due to a US specific requirement

6.6 - Germany is testing due to a Czech requirement (also an EC

requirement)

columns 6.2 - 6.5 refer to the legislation imposing that the test be carried out and Note:

not to the body which has issued the actual test method, guideline or protocol.

Example: a test required by French legislation and carried out in Belgium according to an

ISO protocol must be coded as a national (FR) legislative requirement and be

entered into column 6.2 in the tables submitted by Belgium.

Footnotes: EC Member States: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden, United Kingdom

Member Countries of Council of Europe (non-EC): Albania, Andorra, Bulgaria, Croatia, Cyprus, Czech Rep., Estonia, Hungary, Iceland, Latvia, Liechtenstein, Lithuania, Malta, Moldova, Norway, Poland, Romania, Russia, San Marino, Slovakia, Slovenia, Switzerland, 'the former Yugoslav Rep. of Macedonia', Turkey, Ukraine

TABLE 7: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS

Types of tests versus species

	7.1		7.2		7.3	7.4	7.5	7.6	7.7	7.8	7.9	7.10	7.11	7.12	7.13
	Species		ub-acute toxicity		Skin	Skin	Eye	Sub-	Carcino-	Develop-	Muta-	Repro-	Toxicity	Other	Total
			(including limit to	est)	irritation	sensitisatio	irritation	chronic and	genicity	mental	genicit	ductive	to aquatic		
						n		chronic toxicity		toxicity	У	toxicity	vertebra- tes not		
								toxicity					included		
													in other		
													columns		
		7.2.1.	7.2.2	7.2.3											
		LD50,	Other lethal	Non lethal											
		LC50	methods	clinical signs											
	20	1001	44000	methods	20.4	7.1	•	4000	0500	455	500	200		0700	0.4540
7.a.	Mice	1201	11332	6873	234	71	0	1298	3596	155	589	389	0	8780	34518
7.b. 7.c.	Rats Guinea-Pigs	667 0	960	8144 37	0 97	0 1222	0	7813 84	4807 0	1619 0	420 0	1352 0	0	5036 4	30818 1444
7.d.	Hamsters	0	0	48	0	0	0	0	0	0	0	0	0	9	57
7.u. 7.e.	Other Rodents	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.f.	Rabbits	0	0	400	147	5	38	64	0	514	0	264	0	194	1626
7.g.	Cats	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.h.	Dogs	0	4	285	0	0	0	657	0	0	0	0	0	47	993
7.i.	Ferrets	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.j.	Other Carnivores	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.k.	Horses, donkeys and cross	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	breds														
7.1.	Pigs	0	0	134	0	0	0	92	0	0	0	0	0	107	333
7.m.	Goats	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.n.	Sheep	0	0	2	0	0	0	0	0	0	0	0	0	12	14
7.o.	Cattle	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.p.	Prosimians	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.q.	New World Monkeys	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.r.	Old World Monkeys	0	1	93	0	0	0	158	0	0	0	0	0	75	327
7.s.	Apes	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.t.	Other Mammals	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.u.	Quail Other birds	0	0	0	1000	0	0	0	0	0	0	0	0	0	0
7.v.		0	0	4840 0	1000	0	0	0	0	0	0	0	0	262 0	6102 0
7.w. 7.x.	Reptiles Amphibians	0	0	0	0	0	0	0	0	42	0	0	0	0	42
7.x. 7.y.	Fish	2035	0	170	0	0	0	1100	0	0	0	0	215	0	3520
7.y. 7.z.	TOTAL	3903	12297	21026	1478	1298	38	11266	8403	2330	1009	2005	215	14526	79794
/ .L.	10171	3903	12231	21020	1410	1230	30	11200	0403	2550	פטטו	2003	213	14020	13134

TABLE 8: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS

Types of tests versus products

	8.1		8.2		8.3	8.4	8.5	8.6	8.7	8.8	8.9	8.10	8.11	8.12	8.13
	Products		nd sub-acute toxi ods (including li		Skin irritation	Skin sensitisatio n	Eye irritation	Sub- chronic and chronic toxicity	Carcino genicity	Develop- mental toxicity	Muta- genicit y	Repro- ductive toxicity	Toxicity to aquatic vertebra- tes not included in other columns	Other	Total
		8.2.1. LD50, LC50	8.2.2 Other lethal methods	8.2.3 Non lethal clinical signs methods											
8.a.	Products/substances or devices for human medicine and dentistry and for veterinary medicine	1317	1673	16992	1444	759	29	9240	1433	1519	712	1688	185	6495	43486
8.b.	Products/substances used or intended to be used mainly in agriculture	0	0	40	0	70	0	0	0	0	0	317	0	0	427
8.c.	Products/substances used or intended to be used mainly in industry	0	58	1053	34	468	9	466	0	769	297	0	0	150	3304
8.d.	Products/substances used or intended to be used mainly in the household	0	0	0	0	0	0	0	0	0	0	0	0	0	0
8.e.	Products/substances used or intended to be used mainly as cosmetics or toiletries	0	0	0	0	0	0	0	0	0	0	0	0	0	0
8.f.	Products/substances used or intended to be used mainly as additives in food for human consumption	0	0	1006	0	0	0	150	0	0	0	0	0	0	1156
8.g.	Products/substances used or intended to be used mainly as additives in food for animal consumption	0	182	0	0	0	0	0	0	0	0	0	0	0	182
8.h.	Potential or actual contaminants in the general environment which do not appear in other columns	2035	400	128	0	0	0	1100	6970	0	0	0	30	214	10877
8.i.	Other toxicological or safety evaluations	551	9984	1807	0	1	0	310	0	42	0	0	0	7667	20362
8.j.	TOTAL	3903	12297	21026	1478	1298	38	11266	8403	2330	1009	2005	215	14526	79794

LATVIA

Statistical data submitted

The statistical data have been submitted by the Ministry of Agriculture – State Food and veterinary service

Comments of Latvian authorities

None

TABLE 1: NUMBER OF ANIMALS USED IN RELATION TO THEIR PLACE OF ORIGIN

Origin versus species

	1.1	1.2	1.3	1.4	1.5	1.6	1.7
	Species	Total	Animals coming from registered	Animals coming from	Animals coming from	Animals coming from	Re-used animals
			breeding or supplying	elsewhere in the EC	Member Countries of the	other origins	
			establishments within the reporting		Council of Europe which are		
			country		parties to the Convention ETS		
					123 (excluding EC Member		
	N. ()(40400	40.400		States)		
1.a.	Mice (Mus musculus)	10480	10480				
1.b.	Rats (Rattus norvegicus)	2376	2376				
1.c.	Guinea-Pigs (Cavia porcellus)	297	297				
1.d.	Hamsters (Mesocricetus)	0					
1.e.	Other Rodents (other Rodentia)						
1.f.	Rabbits (Oryctolagus cuniculus)	166	166				
1.g.	Cats (Felis catus)	0					
1.h.	Dogs (Canis familiaris)	0					
1.i.	Ferrets (Mustela putorius furo)	0					
1.j.	Other Carnivores (other Carnivora)						
1.k.	Horses, donkeys and cross breds (Equidae)						
1.1.	Pigs (Sus)						
1.m.	Goats (Capra)						
1.n.	Sheep (Ovis)						
1.o.	Cattle (Bos)						
1.p.	Prosimians (Prosimia)	0					
1.q.	New World Monkeys (Ceboidea)	0					
1.r.	Old World Monkeys (Cercopithecoidea)	0					
1.s.	Apes (Hominoidea)	0					
1.t.	Other Mammals (other Mammalia)						
1.u.	Quail (Coturnix coturnix)	0					
1.v.	Other birds (other Aves)						
1.w.	Reptiles (Reptilia)						
1.x.	Amphibians (Amphibia)						
1.y.	Fish (Pisces)						
1.z.	TOTAL	13319	13319				

Note 1: Column 1.5 concerns only those Member Countries of the Council of Europe which, at the beginning of the reporting period, are Parties to the Convention ETS 123. Thus an updated list of those countries has to be used when filling in this column.

Note 2: Only the white boxes need to be completed.

Note 3: The number of re-used animals in column 1.7 should be excluded from the total in the column 1.2

TABLE 2: NUMBER OF ANIMALS USED IN EXPERIMENTS FOR SELECTED PURPOSES

Purpose versus species

					i pose versus s					
	2.1	2.2	2.3	2.4	2.5	2.6	2.7	2.8	2.9	2.10
	Species	Biological	Research and	Production and	Production and	Toxicological	Diagnosis of	Education and	Other	Total
		studies of a	development of	quality control of	quality control of	and other safety	disease	training		
		fundamenta	products and	products and	products and	evaluations				
		l nature	devices for human	devices for	devices for	(including				
			medicine and	human medicine	veterinary	safety				
			dentistry and for	and dentistry	medicine	evaluation of				
			veterinary			products and				
			medicine			devices for				
			(excluding			human				
			toxicological and			medicine and				
			other safety			dentistry and				
			evaluations			for veterinary				
			counted in column			medicine)				
_	5.51		2.6)							10100
2.a.	Mice	2352	3068	2800			1494	766		10480
2.b.	Rats	265	1105	613		90	126	177		2376
2.c.	Guinea-Pigs	57					240			297
2.d.	Hamsters									0
2.e.	Other Rodents									0
2.f.	Rabbits	121					45			166
2.g.	Cats									0
2.h.	Dogs									0
2.i.	Ferrets									0
2.j.	Other Carnivores									0
2.k.	Horses, donkeys and cross									0
	breds									
2.1.	Pigs									0
2.m.	Goats									0
2.n.	Sheep									0
2.o.	Cattle									0
2.p.	Prosimians									0
2.q.	New World Monkeys									0
2.r.	Old World Monkeys									0
2.s.	Apes									0
2.t.	Other Mammals									0
2.u.	Ouail									0
2.u. 2.v.	Other birds									0
2.w.	Reptiles									0
										0
2.x.	Amphibians									0
2.y.	Fish	0705	4470	0.440	•	20	4005	0.40	0	
2.z.	TOTAL	2795	4173	3413	0	90	1905	943	0	13319

TABLE 3: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS

Products versus species

	3.1	3.2	3.3	3.4	3.5	3.6	3.7	3.8	3.9	3.10	3.11
	Species	Products/	Products/	Products/	Products/	Products/	Products/	Products/	Potential or	Other toxico-	Total
	-	substances or	substances	substances	substances	substances	substances	substances	actual contami-	logical or	
		devices for	used or	used or	used or	used or	used or	used or	nants in the	safety	
		human	intended to	intended to	intended to	intended to	intended to be	intended to be	general envi-	evaluations	
		medicine and	be used	be used	be used	be used	used mainly	used mainly	ronment which		
		dentistry and	mainly in	mainly in	mainly in	mainly as	as additives in	as additives in	do not appear in		
		for veterinary	agriculture	industry	the	cosmetics	food for	food for	other columns		
		medicine			household	or toiletries	human	animal			
							consumption	consumption			
3.a.	Mice										0
3.b.	Rats									90	90
3.c.	Guinea-Pigs										0
3.d.	Hamsters										0
3.e.	Other Rodents										0
3.f.	Rabbits										0
3.g.	Cats										0
3.h.	Dogs										0
3.i.	Ferrets										0
3.j.	Other Carnivores										0
3.k.	Horses, donkeys and cross breds										0
3.1.	Pigs										0
3.m.	Goats										0
3.n.	Sheep										0
3.0.	Cattle										0
3.p.	Prosimians										0
3.q.	New World Monkeys										0
3.r.	Old World Monkeys										0
3.s.	Apes										0
3.t.	Other Mammals										0
3.u.	Quail										0
3.v.	Other birds										0
3.w.	Reptiles										0
3.x.	Amphibians										0
3.y.	Fish										0
3.z.	TOTAL	0	0	0	0	0	0	0	0	90	90

TABLE 4: NUMBER OF ANIMALS USED IN EXPERIMENTS FOR STUDIES ON HUMAN AND ANIMAL DISEASES

Main categories versus species

	4.1	4.2	4.3	4.4	4.5	4.6	4.7
	Species	Human cardiovascular	Human nervous and	Human cancer (excluding	Other human diseases	Studies specific to animal	Total
		diseases	mental disorders	evaluations of carcinogenic		diseases	
				hazards or risks)			
4.a.	Mice						0
4.b.	Rats						0
4.c.	Guinea-Pigs						0
4.d.	Hamsters						0
4.e.	Other Rodents						0
4.f.	Rabbits						0
4.g.	Cats						0
4.h.	Dogs						0
4.i.	Ferrets						0
4.j.	Other Carnivores						0
4.k.	Horses, donkeys and cross breds						0
4.1.	Pigs						0
4.m.	Goats						0
4.n.	Sheep						0
4.0.	Cattle						0
4.p.	Prosimians						0
4.q.	New World Monkeys						0
4.r.	Old World Monkeys						0
4.s.	Apes						0
4.t.	Other Mammals						0
4.u.	Quail						0
4.v.	Other birds						0
4.w.	Reptiles						0
4.x.	Amphibians						0
4.y.	Fish						0
4.z.	TOTAL	0	0	0	0	0	0

TABLE 5: NUMBER OF ANIMALS USED IN PRODUCTION AND QUALITY CONTROL OF PRODUCTS AND DEVICES FOR HUMAN MEDICINE AND DENTISTRY AND FOR VETERINARY MEDICINE

Regulatory requirements versus species

	<i>f</i> 1	5.2		full circuits versus sp		5.6	5.7	<i>5</i> 0
	5.1 Species	5.2 National legislation specific to a single EC	5.3 EC legislation including European	5.4 Member Country of Council of Europe (but not EC)	5.5 Other legislation	5.6 Any combination of 5.2/5.3/5.4/5.5	5.7 No regulatory requirements	5.8 Total
		Member State	Pharmacopoeia	legislation		3.2/ 3.3/ 3.4/ 3.3	requirements	
		1)	(requirements)	2)				
5.a.	Mice	1)	(requirements)	2)		2800		2800
5.b.	Rats					613		613
5.c.	Guinea-Pigs					013		013
5.d.	Hamsters							0
5.e.	Other Rodents							0
5.f.	Rabbits							0
5.g.	Cats							0
5.h.	Dogs							0
5.i.	Ferrets							0
5.j.	Other Carnivores							0
5.k.	Horses, donkeys and cross breds							0
5.1.	Pigs							0
5.m.	Goats							0
5.n.	Sheep							0
5.0.	Cattle							0
5.p.	Prosimians							0
5.q.	New World Monkeys							0
5.r.	Old World Monkeys							0
5.s.	Apes							0
5.t.	Other Mammals							0
5.u.	Quail							0
5.v.	Other birds							0
5.w.	Reptiles							0
5.x.	Amphibians							0
5.y.	Fish							0
5.y.	TOTAL	0	0	0	0	3413	0	3413
J.L.	1011E	ı	<u> </u>		U	0110	U	0+10

Examples:

5.2 – France is testing due to a UK (or FR) specific requirement

5.3 - UK is testing according to EC legislation

5.4 – Spain is testing due to a Hungarian requirement

5.5 – Sweden is testing due to a US specific requirement

5.6 - Germany is testing due to a Czech requirement (also an EC requirement)

Note: columns 5.2 - 5.5 refer to the legislation imposing that the test be carried out and

not to the body which has issued the actual test method, guideline or protocol.

Example: a test required by French legislation and carried out in Belgium according to an

ISO protocol must be coded as a national (FR) legislative requirement and be

entered into column 5.2 in the tables submitted by Belgium.

Footnotes:

- EC Member States: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden, United Kingdom
- Member Countries of Council of Europe (non-EC): Albania, Andorra, Bulgaria, Croatia, Cyprus, Czech Rep., Estonia, Hungary, Iceland, Latvia, Liechtenstein, Lithuania, Malta, Moldova, Norway, Poland, Romania, Russia, San Marino, Slovakia, Slovenia, Switzerland, 'the former Yugoslay Rep. of Macedonia', Turkey, Ukraine

TABLE 6: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS

Regulatory requirements versus species

	6.1 Species	6.2 National legislation specific to a single EC	6.3 EC legislation including European	6.4 Member Country of Council of Europe (but not EC)	6.5 Other legislation	6.6 Any combination of 6.2/ 6.3/ 6.4/ 6.5	6.7 No regulatory requirements	6.8 Total
		Member State	Pharmacopoeia	legislation		0.2/ 0.3/ 0.4/ 0.3	requirements	
		1)	(requirements)	2)				
6.a.	Mice	1,	(requirements)					0
6.b.	Rats						90	90
6.c.	Guinea-Pigs						00	0
6.d.	Hamsters							0
6.e.	Other Rodents							0
6.f.	Rabbits							0
6.g.	Cats							0
6.h.	Dogs							0
6.i.	Ferrets							0
6.j.	Other Carnivores							0
6.k.	Horses, donkeys and cross breds							0
6.1.	Pigs							0
6.m.	Goats							0
6.n.	Sheep							0
6.o.	Cattle							0
6.p.	Prosimians							0
6.q.	New World Monkeys							0
6.r.	Old World Monkeys							0
6.s.	Apes							0
6.t.	Other Mammals							0
6.u.	Quail							0
6.v.	Other birds							0
6.w.	Reptiles							0
6.x.	Amphibians							0
6.y.	Fish							0
6.z.	TOTAL	0	0	0	0	0	90	90

Examples:

6.2 – France is testing due to a UK (or FR) specific requirement

6.3 - UK is testing according to EC legislation

6.4 – Spain is testing due to a Hungarian requirement

6.5 – Sweden is testing due to a US specific requirement

6.6 - Germany is testing due to a Czech requirement (also an EC

requirement)

Note: columns 6.2 - 6.5 refer to the legislation imposing that the test be carried out and

not to the body which has issued the actual test method, guideline or protocol.

Example: a test required by French legislation and carried out in Belgium according to an ISO protocol must be coded as a national (FR) legislative requirement and be

entered into column 6.2 in the tables submitted by Belgium.

Footnotes:

EC Member States: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden, United Kingdom

Member Countries of Council of Europe (non-EC): Albania, Andorra, Bulgaria, Croatia, Cyprus, Czech Rep., Estonia, Hungary, Iceland, Latvia, Liechtenstein, Lithuania, Malta, Moldova, Norway, Poland, Romania, Russia, San Marino, Slovakia, Slovenia, Switzerland, 'the former Yugoslav Rep. of Macedonia', Turkey, Ukraine

TABLE 7: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS

Types of tests versus species

	7.1 Species	Acute and s	7.2 ub-acute toxicity (including limit to	testing methods est)	7.3 Skin irritation	7.4 Skin sensitisatio n	7.5 Eye irritation	7.6 Sub- chronic and chronic toxicity	7.7 Carcino- genicity	7.8 Develop- mental toxicity	7.9 Muta- genicit y	7.10 Reproductive toxicity	7.11 Toxicity to aquatic vertebra- tes not included in other columns	7.12 Other	7.13 Total
		7.2.1. LD50, LC50	7.2.2 Other lethal methods	7.2.3 Non lethal clinical signs methods									Coramino		
7.a.	Mice														0
7.b.	Rats											90			90
7.c.	Guinea-Pigs														0
7.d.	Hamsters														0
7.e.	Other Rodents														0
7.f.	Rabbits														0
7.g.	Cats														0
7.h.	Dogs														0
7.i.	Ferrets														0
7.j.	Other Carnivores														0
7.k.	Horses, donkeys and cross breds														0
7.1.	Pigs														0
7.m.	Goats														0
7.n.	Sheep														0
7.o.	Cattle														0
7.p.	Prosimians														0
7.q.	New World Monkeys														0
7.r.	Old World Monkeys														0
7.s.	Apes														0
7.t.	Other Mammals														0
7.u.	Quail														0
7.v.	Other birds														0
7.w.	Reptiles														0
7.x.	Amphibians														0
7.y.	Fish														0
7.z.	TOTAL	0	0	0	0	0	0	0	0	0	0	90	0	0	90

TABLE 8: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS

Types of tests versus products

	8.1 Products		8.2 nd sub-acute tox ods (including li		8.3 Skin irritation	8.4 Skin sensitisatio n	8.5 Eye irritation	8.6 Sub- chronic and chronic toxicity	8.7 Carcino genicity	8.8 Develop- mental toxicity	8.9 Muta- genicit y	8.10 Reproductive toxicity	8.11 Toxicity to aquatic vertebra- tes not included in other columns	8.12 Other	8.13 Total
		8.2.1. LD50, LC50	8.2.2 Other lethal methods	8.2.3 Non lethal clinical signs methods											
8.a.	Products/substances or devices for human medicine and dentistry and for veterinary medicine											90			90
8.b.	Products/substances used or intended to be used mainly in agriculture														0
8.c.	Products/substances used or intended to be used mainly in industry														0
8.d.	Products/substances used or intended to be used mainly in the household														0
8.e.	Products/substances used or intended to be used mainly as cosmetics or toiletries														0
8.f.	Products/substances used or intended to be used mainly as additives in food for human consumption														0
8.g.	Products/substances used or intended to be used mainly as additives in food for animal consumption														0
8.h.	Potential or actual contaminants in the general environment which do not appear in other columns														0
8.i.	Other toxicological or safety evaluations														0
8.j.	TOTAL	0	0	0	0	0	0	0	0	0	0	90	0	0	90

LITHUANIA

Statistical data submitted

The statistical data have been submitted by the State Food and Veterinary service – Animal welfare department - Siesiku 19 LT-2010 Vilnius

Comments of Lithuanian authorities

None

TABLE 1: NUMBER OF ANIMALS USED IN RELATION TO THEIR PLACE OF ORIGIN

Origin versus species

	1.1 Species	1.2 Total	1.3 Animals coming from registered breeding or supplying establishments within the reporting country	1.4 Animals coming from elsewhere in the EC	1.5 Animals coming from Member Countries of the Council of Europe which are parties to the Convention ETS 123 (excluding EC Member States)	1.6 Animals coming from other origins	1.7 Re-used animals
1.a.	Mice (Mus musculus)	5116	5116				
1.b.	Rats (Rattus norvegicus)	493	493				
1.c.	Guinea-Pigs (Cavia porcellus)	0					
1.d.	Hamsters (Mesocricetus)	0					
1.e.	Other Rodents (other Rodentia)						
1.f.	Rabbits (Oryctolagus cuniculus)	158	158				
1.g.	Cats (Felis catus)	0					
1.h.	Dogs (Canis familiaris)	0					
1.i.	Ferrets (Mustela putorius furo)	0					
1.j.	Other Carnivores (other Carnivora)						
1.k.	Horses, donkeys and cross breds (Equidae)						
1.1.	Pigs (Sus)						
1.m.	Goats (Capra)						
1.n.	Sheep (Ovis)						
1.o.	Cattle (Bos)						
1.p.	Prosimians (<i>Prosimia</i>)	0					
1.q.	New World Monkeys (Ceboidea)	0					
1.r.	Old World Monkeys (Cercopithecoidea)	0					
1.s.	Apes (Hominoidea)	0					
1.t.	Other Mammals (other Mammalia)						
1.u.	Quail (Coturnix coturnix)	0					
1.v.	Other birds (other Aves)						
1.w.	Reptiles (Reptilia)						
1.x.	Amphibians (Amphibia)						
1.y.	Fish (Pisces)						
1.z.	TOTAL	5767					

Note 1: Column 1.5 concerns only those Member Countries of the Council of Europe which, at the beginning of the reporting period, are Parties to the Convention ETS 123. Thus an updated list of those countries has to be used when filling in this column.

Note 2: Only the white boxes need to be completed.

Note 3: The number of re-used animals in column 1.7 should be excluded from the total in the column 1.2

TABLE 2: NUMBER OF ANIMALS USED IN EXPERIMENTS FOR SELECTED PURPOSES
Purpose versus species

					i pose versus s					
	2.1	2.2	2.3	2.4	2.5	2.6	2.7	2.8	2.9	2.10
	Species	Biological	Research and	Production and	Production and	Toxicological	Diagnosis of	Education and	Other	Total
		studies of a	development of	quality control of	quality control of	and other safety	disease	training		
		fundamenta	products and	products and	products and	evaluations				
		l nature	devices for human	devices for	devices for	(including				
			medicine and	human medicine	veterinary	safety				
			dentistry and for	and dentistry	medicine	evaluation of				
			veterinary			products and				
			medicine			devices for				
			(excluding			human				
			toxicological and			medicine and				
			other safety			dentistry and				
			evaluations			for veterinary				
			counted in column			medicine)				
_) (°	4770	2.6)			220	0500	420		F44C
2.a.	Mice	1773				330 120	2583	430 50		5116
2.b.	Rats	323				120		50		493
2.c.	Guinea-Pigs									0
2.d.	Hamsters									0
2.e.	Other Rodents									0
2.f.	Rabbits	96				62				158
2.g.	Cats									0
2.h.	Dogs									0
2.i.	Ferrets									0
2.j.	Other Carnivores									0
2.k.	Horses, donkeys and cross									0
	breds									
2.1.	Pigs									0
2.m.	Goats									0
2.n.	Sheep									0
2.o.	Cattle									0
2.p.	Prosimians									0
2.q.	New World Monkeys									0
2.r.	Old World Monkeys									0
2.s.	Apes									0
2.t.	Other Mammals									0
2.u.	Quail									0
2.v.	Other birds									0
2.w.	Reptiles									0
2.x.	Amphibians									0
2.y.	Fish									0
2.z.	TOTAL	2192	0	0	0	512	2583	480	0	5767
				Ļ		ļ		,00		2.01

TABLE 3: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS

Products versus species

	3.1	3.2	3.3	3.4	3.5	3.6	3.7	3.8	3.9	3.10	3.11
	Species	Products/	Products/	Products/	Products/	Products/	Products/	Products/	Potential or	Other toxico-	Total
		substances or	substances	substances	substances	substances	substances	substances	actual contami-	logical or	
		devices for	used or	used or	used or	used or	used or	used or	nants in the	safety	
		human	intended to	intended to	intended to	intended to	intended to be	intended to be	general envi-	evaluations	
		medicine and	be used	be used	be used	be used	used mainly	used mainly	ronment which		
		dentistry and	mainly in	mainly in	mainly in	mainly as	as additives in	as additives in	do not appear in		
		for veterinary	agriculture	industry	the	cosmetics	food for	food for	other columns		
		medicine			household	or toiletries	human	animal			
	2.0						consumption	consumption			
3.a.	Mice		330								330
3.b.	Rats		120								120
3.c.	Guinea-Pigs										0
3.d.	Hamsters										0
3.e.	Other Rodents										0
3.f.	Rabbits	62									62
3.g.	Cats										0
3.h.	Dogs										0
3.i.	Ferrets										0
3.j.	Other Carnivores										0
3.k.	Horses, donkeys and cross breds										0
3.1.	Pigs										0
3.m.	Goats										0
3.n.	Sheep										0
3.o.	Cattle										0
3.p.	Prosimians										0
3.q.	New World Monkeys										0
3.r.	Old World Monkeys										0
3.s.	Apes										0
3.t.	Other Mammals										0
3.u.	Quail										0
3.v.	Other birds										0
3.w.	Reptiles										0
3.x.	Amphibians										0
J.A.											
3.y.	Fish										0

TABLE 4: NUMBER OF ANIMALS USED IN EXPERIMENTS FOR STUDIES ON HUMAN AND ANIMAL DISEASES

Main categories versus species

	4.1	4.2	4.3	4.4	4.5	4.6	4.7
	Species	Human cardiovascular	Human nervous and	Human cancer (excluding	Other human diseases	Studies specific to animal	Total
		diseases	mental disorders	evaluations of carcinogenic		diseases	
				hazards or risks)			
4.a.	Mice				2583		2583
	Rats						0
4.c.	Guinea-Pigs						0
	Hamsters						0
4.e.	Other Rodents						0
4.f.	Rabbits						0
4.g.	Cats						0
4.h.	Dogs						0
	Ferrets						0
4.j.	Other Carnivores						0
4.k.	Horses, donkeys and cross breds						0
	Pigs						0
4.m.	Goats						0
4.n.	Sheep						0
4.0.	Cattle						0
4.p.	Prosimians						0
4.q.	New World Monkeys						0
4.r.	Old World Monkeys						0
4.s.	Apes						0
4.t.	Other Mammals						0
4.u.	Quail						0
4.v.	Other birds						0
4.w.	Reptiles						0
4.x.	Amphibians						0
	Fish						0
4.z.	TOTAL	0	0	0	2583	0	2583

TABLE 5: NUMBER OF ANIMALS USED IN PRODUCTION AND QUALITY CONTROL OF PRODUCTS AND DEVICES FOR HUMAN MEDICINE AND DENTISTRY AND FOR VETERINARY MEDICINE

Regulatory requirements versus species

		5.0		fair chickes versus sp				
	5.1 Species	5.2 National legislation specific to a single EC Member State	5.3 EC legislation including European Pharmacopoeia	5.4 Member Country of Council of Europe (but not EC) legislation 2)	5.5 Other legislation	5.6 Any combination of 5.2/ 5.3/ 5.4/ 5.5	5.7 No regulatory requirements	5.8 Total
<u> </u>	3.01	1)	(requirements)	2)				
5.a.	Mice							0
5.b.	Rats							0
5.c.	Guinea-Pigs							0
5.d.	Hamsters							0
5.e.	Other Rodents							0
5.f.	Rabbits							0
5.g.	Cats							0
5.h.	Dogs							0
5.i.	Ferrets							0
5.j.	Other Carnivores							0
5.k.	Horses, donkeys and cross breds							0
5.1.	Pigs							0
5.m.	Goats							0
5.n.	Sheep							0
5.o.	Cattle							0
5.p.	Prosimians							0
5.q.	New World Monkeys							0
5.r.	Old World Monkeys							0
5.s.	Apes							0
5.t.	Other Mammals							0
5.u.	Quail							0
5.v.	Other birds							0
5.w.	Reptiles							0
5.x.	Amphibians							0
5.y.	Fish							0
5.z.	TOTAL	0	0	0	0	0	0	0
			1	1				

Examples:

Footnotes:

5.2 – France is testing due to a UK (or FR) specific requirement

5.3 - UK is testing according to EC legislation

5.4 – Spain is testing due to a Hungarian requirement

5.5 – Sweden is testing due to a US specific requirement

5.6 - Germany is testing due to a Czech requirement (also an EC

requirement)

Note: columns 5.2 - 5.5 refer to the legislation imposing that the test be carried out and

not to the body which has issued the actual test method, guideline or protocol.

Example: a test required by French legislation and carried out in Belgium according to an

ISO protocol must be coded as a national (FR) legislative requirement and be

entered into column 5.2 in the tables submitted by Belgium.

1) EC Member States: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden, United Kingdom

2) Member Countries of Council of Europe (non-EC): Albania, Andorra, Bulgaria, Croatia, Cyprus, Czech Rep., Estonia, Hungary, Iceland, Latvia, Liechtenstein, Lithuania, Malta, Moldova, Norway, Poland, Romania, Russia, San Marino, Slovakia, Slovenia, Switzerland, 'the former Yugoslav Rep. of Macedonia', Turkey, Ukraine

TABLE 6: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS

Regulatory requirements versus species

	6.1	6.2	6.3	6.4	6.5	6.6	6.7	6.8
	Species	National legislation	EC legislation	Member Country of Council	Other legislation	Any combination of	No regulatory	Total
		specific to a single EC	including European	of Europe (but not EC)		6.2/ 6.3/ 6.4/ 6.5	requirements	
		Member State	Pharmacopoeia	legislation				
		1)	(requirements)	2)				
6.a.	Mice		330					330
6.b.	Rats		120					120
6.c.	Guinea-Pigs							0
6.d.	Hamsters							0
6.e.	Other Rodents							0
6.f.	Rabbits		62					62
6.g.	Cats							0
6.h.	Dogs							0
6.i.	Ferrets							0
6.j.	Other Carnivores							0
6.k.	Horses, donkeys and cross breds							0
6.1.	Pigs							0
6.m.	Goats							0
6.n.	Sheep							0
6.0.	Cattle							0
6.p.	Prosimians							0
6.q.	New World Monkeys							0
6.r.	Old World Monkeys							0
6.s.	Apes							0
6.t.	Other Mammals							0
6.u.	Quail							0
6.v.	Other birds							0
6.w.	Reptiles							0
6.x.	Amphibians							0
6.y.	Fish							0
6.z.	TOTAL	0	512	0	0	0	0	512

Examples:

6.2 – France is testing due to a UK (or FR) specific requirement

6.3 - UK is testing according to EC legislation

6.4 – Spain is testing due to a Hungarian requirement

6.5 – Sweden is testing due to a US specific requirement

6.6 - Germany is testing due to a Czech requirement (also an EC

requirement)

Note: columns 6.2 - 6.5 refer to the legislation imposing that the test be carried out and

not to the body which has issued the actual test method, guideline or protocol.

Example: a test required by French legislation and carried out in Belgium according to an

ISO protocol must be coded as a national (FR) legislative requirement and be

entered into column 6.2 in the tables submitted by Belgium.

Footnotes:

EC Member States: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden, United Kingdom

Member Countries of Council of Europe (non-EC): Albania, Andorra, Bulgaria, Croatia, Cyprus, Czech Rep., Estonia, Hungary, Iceland, Latvia, Liechtenstein, Lithuania, Malta, Moldova, Norway, Poland, Romania, Russia, San Marino, Slovakia, Slovenia, Switzerland, 'the former Yugoslav Rep. of Macedonia', Turkey, Ukraine

TABLE 7: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS

Types of tests versus species

	7.1 Species	Acute and s	7.2 ub-acute toxicity t (including limit to	testing methods est)	7.3 Skin irritation	7.4 Skin sensitisatio n	7.5 Eye irritation	7.6 Sub- chronic and chronic toxicity	7.7 Carcino- genicity	7.8 Develop- mental toxicity	7.9 Muta- genicit y	7.10 Reproductive toxicity	7.11 Toxicity to aquatic vertebra- tes not included in other	7.12 Other	7.13 Total
		7.2.1. LD50, LC50	7.2.2 Other lethal methods	7.2.3 Non lethal clinical signs methods									columns		
7.a.	Mice			100										230	330
7.b.	Rats			60										60	120
7.c.	Guinea-Pigs														0
7.d.	Hamsters														0
7.e.	Other Rodents														0
7.f.	Rabbits													62	62
7.g.	Cats														0
7.h.	Dogs														0
7.i.	Ferrets														0
7.j.	Other Carnivores														0
7.k.	Horses, donkeys and cross breds														0
7.1.	Pigs														0
7.m.	Goats														0
7.n.	Sheep														0
7.o.	Cattle														0
7.p.	Prosimians														0
7.q.	New World Monkeys														0
7.r.	Old World Monkeys														0
7.s.	Apes														0
7.t.	Other Mammals														0
7.u.	Quail	·													0
7.v.	Other birds														0
7.w.	Reptiles														0
7.x.	Amphibians														0
7.y.	Fish														0
7.z.	TOTAL	0	0	160	0	0	0	0	0	0	0	0	0	352	512

TABLE 8: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS

Types of tests versus products

	8.1 Products		8.2 nd sub-acute tox ods (including li		8.3 Skin irritation	8.4 Skin sensitisatio n	8.5 Eye irritation	8.6 Sub- chronic and chronic toxicity	8.7 Carcino genicity	8.8 Develop- mental toxicity	8.9 Muta- genicit y	8.10 Reproductive toxicity	8.11 Toxicity to aquatic vertebra- tes not included in other columns	8.12 Other	8.13 Total
		8.2.1. LD50, LC50	8.2.2 Other lethal methods	8.2.3 Non lethal clinical signs methods											
8.a.	Products/substances or devices for human medicine and dentistry and for veterinary medicine							_						62	62
8.b.	Products/substances used or intended to be used mainly in agriculture			160										290	450
8.c.	Products/substances used or intended to be used mainly in industry														0
8.d.	Products/substances used or intended to be used mainly in the household														0
8.e.	Products/substances used or intended to be used mainly as cosmetics or toiletries														0
8.f.	Products/substances used or intended to be used mainly as additives in food for human consumption														0
8.g.	Products/substances used or intended to be used mainly as additives in food for animal consumption														0
8.h.	Potential or actual contaminants in the general environment which do not appear in other columns														0
8.i.	Other toxicological or safety evaluations														0
8.j.	TOTAL	0	0	160	0	0	0	0	0	0	0	0	0	352	512

LUXEMBOURG

Statistical data submitted

The statistical data have been submitted by the "Ministère de l'Agriculture, de la viticulture et du developpement rural. Administration des Services Vétérinaires" (Ministry of Agriculture, viticulture and rural development. Administration of Veterinary Services)

Comments of Luxembourg authorities

Comments on statistical data on the use of laboratory animals in the Grand Duchy of Luxembourg in 2005

To DG Environment D.1.

- 2 experimentation projects were registered in Luxembourg in 2005 compared to 1 project in 2004.
- In comparison with 2004, a 62% decrease in the number of laboratory animals used has been recorded (280 more mice, but 500 fewer chicks and 1 800 fewer cotton rats).
- Responsibility for monitoring animal welfare lies with a veterinary inspector, who carries out at least 2 inspections per year per requested experimentation project.
- Detection infrastructure and the handling of laboratory animals comply with animal welfare requirements.
- The experiments are intended for:
- a) an immunological study of the protective efficiency and the antigenicity of antigens to improve vaccination strategies and diagnostic procedures for specific diseases;
- b) projects relating to immunology and immunodeficiency.

Director of the Veterinary

Services Administration

Dr Arthur Besch

Remark:

Please note that only relevant EU tables containing data are included in this report. No uses of animals were reported in Tables 3-8.

TABLE 1: NUMBER OF ANIMALS USED IN RELATION TO THEIR PLACE OF ORIGIN

Origin versus species

	1.1	1.2	1.3	1.4	1.5	1.6	1.7
	Species	Total	Animals coming from registered	Animals coming from	Animals coming from	Animals coming from	Re-used animals
			breeding or supplying	elsewhere in the EC	Member Countries of the	other origins	
			establishments within the reporting		Council of Europe which are		
			country		parties to the Convention ETS		
					123 (excluding EC Member		
1	Nr. (11	0000	2000		States)		
1.a.	Mice (Mus musculus)	3280	3280				
1.b.	Rats (Rattus norvegicus)	720	720				
1.c.	Guinea-Pigs (Cavia porcellus)	100	100				
1.d.	Hamsters (Mesocricetus)	0					
1.e.	Other Rodents (other Rodentia)						
1.f.	Rabbits (Oryctolagus cuniculus)	20	20				
1.g.	Cats (Felis catus)	0					
1.h.	Dogs (Canis familiaris)	0					
1.i.	Ferrets (Mustela putorius furo)	0					
1.j.	Other Carnivores (other Carnivora)						
1.k.	Horses, donkeys and cross breds (Equidae)						
1.1.	Pigs (Sus)						
1.m.	Goats (Capra)						
1.n.	Sheep (Ovis)						
1.o.	Cattle (Bos)						
1.p.	Prosimians (<i>Prosimia</i>)	0					
1.q.	New World Monkeys (Ceboidea)	0					
1.r.	Old World Monkeys (Cercopithecoidea)	0					
1.s.	Apes (Hominoidea)	0					
1.t.	Other Mammals (other Mammalia)						
1.u.	Quail (Coturnix coturnix)	0					
1.v.	Other birds (other Aves)						
1.w.	Reptiles (Reptilia)						
1.x.	Amphibians (Amphibia)						
1.y.	Fish (Pisces)						
1.z.	TOTAL	4120	4120				

Note 1: Column 1.5 concerns only those Member Countries of the Council of Europe which, at the beginning of the reporting period, are Parties to the Convention ETS 123. Thus an updated list of those countries has to be used when filling in this column.

Note 2: Only the white boxes need to be completed.

Note 3: The number of re-used animals in column 1.7 should be excluded from the total in the column 1.2

TABLE 2: NUMBER OF ANIMALS USED IN EXPERIMENTS FOR SELECTED PURPOSES

Purpose versus species

					•					
	2.1	2.2	2.3	2.4	2.5	2.6	2.7	2.8	2.9	2.10
	Species	Biological	Research and	Production and	Production and	Toxicological	Diagnosis of	Education and	Other	Total
		studies of a	development of	quality control of	quality control of	and other safety	disease	training		
		fundamenta	products and	products and	products and	evaluations				
		1 nature	devices for human	devices for	devices for	(including				
			medicine and	human medicine	veterinary	safety				
			dentistry and for	and dentistry	medicine	evaluation of				
			veterinary			products and				
			medicine			devices for				
			(excluding			human				
			toxicological and			medicine and				
			other safety			dentistry and				
			evaluations			for veterinary				
			counted in column			medicine)				
2	NC.	200	2.6)							2200
2.a.	Mice	280	3000							3280
2.b.	Rats Guinea-Pigs	320	400							720
2.c.			100							100
2.d.	Hamsters									0
2.e.	Other Rodents									0
2.f.	Rabbits		20							20
2.g.	Cats									0
2.h.	Dogs									0
2.i.	Ferrets									0
2.j.	Other Carnivores									0
2.k.	Horses, donkeys and cross									0
	breds									
2.1.	Pigs									0
2.m.	Goats									0
2.n.	Sheep									0
2.o.	Cattle									0
2.p.	Prosimians									0
2.q.	New World Monkeys									0
2.r.	Old World Monkeys									0
2.s.	Apes									0
2.t.	Other Mammals									0
2.u.	Quail									0
2.v.	Other birds									0
2.w.	Reptiles									0
2.x.	Amphibians									0
2.y.	Fish									0
2.z.	TOTAL	600	3520	0	0	0	0	0	0	4120
∠ .∠.		000	5520	0	0	0	0	U	U	7120

MALTA

No animals were used in Malta in 2005 for experimental or other scientific purposes.

THE NETHERLANDS

Statistical data submitted

The statistical data have been submitted by the "Keuringsdienst van Waren, Ministerie voor Volksgezondheid, Welzijn en Sport" (Inspectorate for Goods, Ministry for Public Health, Welfare and Sports

Comments of the Dutch authorities

National vs EU statistics

Since the first national report was published in 1978 the total number of animal experiments has never been as low as in 2005. After a faster decline the first 10-15 years the decrease slowed down the last 10 years. However the overall tendency still seems to be decreasing though in a slower pace.

The national statistics are published annually including the eight tables constructed in accordance with the EU system. The latest reports can be found at www.vwa.nl. The Dutch national statistics differ slightly form the Dutch EU-contribution. The numbers in the national statistics are higher due to the following:

- 1. In addition to the EU statistics, killing animals solely for harvesting tissues or organs is considered to be an experiment and contributes to the statistics. In 2005 a total number of 55.144 animals (i.e. 7% of the total number of animals used) were killed for this purpose, without any procedures or techniques connected with the experiment performed on them before their death.
- 2. Furthermore the Dutch statistics are based on the number of experiments performed and not so much on the number of animals involved. Therefore re-use is included as well. It clearly influences the statistics, hence each and every time the animal was used will contribute to the total number of experiments. In 2005 28.717 animal experiments were conducted on animals that had already been used. These animals were not included in the EU statistics.

The national statistics include 19 tables relating species to different topics. Like e.g. origin of the animal, type of experiment, severity score, mandatory testing, anaesthesia, pain alleviation, etc. Furthermore 14 tables on type of experiment versus species and their origin, safety testing and special techniques, etc are published. Special tables are made per university (hospital and academia alike) 15 in total and 2 tables on research performed for the ministry of Defence.

Severity scoring

All animal experiments have to go through a procedure of ethical reviewing prior to the start of the experiment. Part of the ethical reviewing is assessing by the responsible researcher, proposed expected severity score. During the experiment the animals are closely watched also to assess the actually experienced discomfort, harm, distress, etc. The experienced severity score is the one that is registered. The Dutch law recognises 6 severity bands:

- minor (35.5% of the experiments in 2005)

- minor/moderate (29.2% of the experiments in 2005)
- moderate (22.0% of the experiments in 2005)
- moderate/severe (8.8% of the experiments in 2005)
- severe (4.5% of the experiments in 2005)
- very severe (0.1% of the experiments in 2005)

Primates

In 2005 327 primates were used (50 new world primates and 277 old world primates) for the first time, which is 0.62%. A further 5 new world primates and 372 old world primates were re-used, taking the total number of animal experiments conducted on primates op to 704 (0.11% of the total number of animal experiments).

Since 2003 it has been prohibited to perform animal experiments on great apes (behaviour-studies consisting solely of observing the animals in their normal surroundings and which do not include any discomfort, harm, distress, etc. is not considered to be an experiment. Therefore these studies are exempted from the prohibition). In 2004 the last 6 experiments were conducted on chimpanzees, hence in 2005 no experiments on great apes were performed nor will there be any in the foreseeable future.

Inspectorate and inspections

The Food and Consumer Product Safety Authority (VWA) is responsible for enforcement of the legislation concerning laboratory animal welfare. The VWA conducted a total of 554 inspections in 2005 of which approximately 40% was unannounced beforehand. These inspections clearly showed that the regulations with direct regard to the welfare of the animals were in general well abided by.

In several cases infringements were detected. Depending on the severity of the infringement appropriate action was taken. In six cases the licence-holder received a written warning including a deadline for solving the problem. These licence-holders were told to solve the indicated infringement before a certain date. In every case the problems were solved when the inspector re-visited the licence-holder after the notified deadline. These infringements consisted of:

- housing of animals;
- entering remarks in a so-called welfare diary (which has to be present at the animal room to be used for recording all relevant welfare remarks);
- handling of and caring for the animals by not yet licensed personnel;
- conducting experiments on animals not bred/delivered by a licensed breeder without an exoneration by the VWA
- Conducting an experiment not according to the project plan, which had received a positive advice of the ethical review committee.

Comparing 2005 with 2004

In 2005 fewer experiments were conducted than in 2004. Nearly half of the drop in number of animal experiments was due to a lower number of chicken experiments. This still was the result of the aftermath of the Avian Influenza outbreak in 2003. Many projects were postponed in 2003 due to the restrictions on transport of animals and eggs, hence a low number of chickens appeared in the 2003 statistics. In 2004 making up leeway led to a steep increase in use of chickens. In 2005 the situation was back to normal, thus the number dropped to normal levels.

Type of experiments

Most animal experiments were conducted for developing, producing, checking or verifying of sera, vaccines, drugs, medical or veterinary products (47.3%). Fundamental research was responsible for 44.2% of the total number of animal experiments. Potentially harming effects of substances covered 5.1%, diagnostic procedures 1.4% and education and training 2.0%. (These percentages are all based on the national statistics, hence including re-use and organ harvesting.)

Licence holding establishments

A licence to perform animal experiments is obliged in order to perform any experiment. In 2005 a total of 80 licence-holding establishments were registered by VWA. Three new licences were issued and one licence was terminated on request of the licence-holder.

In order to be allowed to breed an/or deliver laboratory animals a licence is mandatory as well. In 2005 41 establishments were licensed to breed a/o deliver laboratory animals. Most of which also have a licence to perform animal experiments.

TABLE 1: NUMBER OF ANIMALS USED IN RELATION TO THEIR PLACE OF ORIGIN

Origin versus species

1.1	1.2	1.3	1.4	1.5	1.6	1.7
Species	Total	Animals coming from registered	Animals coming from	Animals coming from	Animals coming from	Re-used animals
		breeding or supplying	elsewhere in the EC	Member Countries of the	other origins	
		establishments within the reporting		Council of Europe which are		
		country		parties to the Convention ETS		
				123 (excluding EC Member		
	0.400.40			States)	2010	
1.a. Mice (Mus musculus)	240048	228666	0	7733	3649	5695
1.b. Rats (Rattus norvegicus)	116608	111973	0	4423	212	3357
1.c. Guinea-Pigs (Cavia porcellus)	7479	4319	0	3150	10	46
1.d. Hamsters (Mesocricetus)	5322	4961	0	357	4	13
1.e. Other Rodents (other <i>Rodentia</i>)	3089	1798	0	1167	124	521
1.f. Rabbits (Oryctolagus cuniculus)	8251	7556	0	665	30	663
1.g. Cats (Felis catus)	334	233	0	30	71	14
1.h. Dogs (Canis familiaris)	1049	528	0	98	423	194
1.i. Ferrets (Mustela putorius furo)	256	21	0	50	185	0
1.j. Other Carnivores (other <i>Carnivora</i>)	151	0	0	0	151	0
1.k. Horses, donkeys and cross breds (Equidae)	1705	541	0	0	1164	858
1.1. Pigs (<i>Sus</i>)	9853	4113	540	65	5135	63
1.m. Goats (Capra)	328	114	0	0	214	65
1.n. Sheep (Ovis)	2667	184	0	10	2473	152
1.o. Cattle (Bos)	4410	2602	3	81	1724	429
1.p. Prosimians (<i>Prosimia</i>)	0	0	0	0	0	0
1.q. New World Monkeys (Ceboidea)	50	32	0	18	0	5
1.r. Old World Monkeys (Cercopithecoidea)	277	223	0	35	19	185
1.s. Apes (Hominoidea)	0	0	0	0	0	0
1.t. Other Mammals (other Mammalia)	13	0	0	0	13	0
1.u. Quail (Coturnix coturnix)	152	0	0	152	0	0
1.v. Other birds (other <i>Aves</i>)	111081	15137	26	0	95918	603
1.w. Reptiles (Reptilia)	7	2	0	0	5	0
1.x. Amphibians (Amphibia)	3231	2877	0	7	347	0
1.y. Fish (Pisces)	14838	6906	683	1250	5999	119
1.z. TOTAL	531199	392786	1252	19291	117870	12982

Note 1: Column 1.5 concerns only those Member Countries of the Council of Europe which, at the beginning of the reporting period, are Parties to the Convention ETS 123. Thus an updated list of those countries has to be used when filling in this column.

Note 2: Only the white boxes need to be completed.

Note 3: The number of re-used animals in column 1.7 should be excluded from the total in the column 1.2

TABLE 2: NUMBER OF ANIMALS USED IN EXPERIMENTS FOR SELECTED PURPOSES
Purpose versus species

					ur pose versu					
	2.1	2.2	2.3	2.4	2.5	2.6	2.7	2.8	2.9	2.10
	Species	Biological	Research and	Production and	Production and	Toxicological	Diagnosis of	Education and	Other	Total
		studies of a	development of	quality control of	quality control of	and other safety	disease	training		
		fundamenta	products and	products and	products and	evaluations				
		l nature	devices for human	devices for	devices for	(including				
			medicine and	human medicine	veterinary	safety				
			dentistry and for	and dentistry	medicine	evaluation of				
			veterinary			products and				
			medicine			devices for				
			(excluding			human				
			toxicological and			medicine and				
			other safety			dentistry and				
			evaluations			for veterinary				
			counted in column			medicine)				
2		4.40007	2.6)	4.454.0	40407	0444	0704	0740		0.400.40
2.a.	Mice	143937	47957	14519	16107	6114	8704	2710	0	240048
2.b.	Rats	34904	20931	32029	2769	23100	0	2875	0	116608
2.c.	Guinea-Pigs	609	1553	1223	3621	429	3	41	0	7479
2.d.	Hamsters	811	94	5	4356	45	0	11	0	5322
2.e.	Other Rodents	197	2781	0	0	0	0	111	0	3089
2.f.	Rabbits	751	1211	88	2222	3920	15	44	0	8251
2.g.	Cats	129	33	0	83	6	0	83	0	334
2.h.	Dogs	166	157	0	287	401	0	38	0	1049
2.i.	Ferrets	136	108	0	0	0	0	12	0	256
2.j.	Other Carnivores	151	0	0	0	0	0	0	0	151
2.k.	Horses, donkeys and cross	2	163	65	1473	0	0	2	0	1705
	breds									
2.1.	Pigs	5336	2482	82	1725	56	0	172	0	9853
2.m.	Goats	221	43	0	0	0	0	64	0	328
2.n.	Sheep	211	194	2179	74	0	0	9	0	2667
2.0.	Cattle	2930	875	53	322	0	0	230	0	4410
2.p.	Prosimians	0	0	0	0	0	0	0	0	0
2.q.	New World Monkeys	13	23	0	0	14	0	0	0	50
2.r.	Old World Monkeys	196	71	10	0	0	0	0	0	277
2.s.	Apes	0	0	0	0	0	0	0	0	0
2.t.	Other Mammals	0	13	0	0	0	0	0	0	13
2.u.	Quail	0	0	0	0	152	0	0	0	152
2.v.	Other birds	34618	28022	333	47775	24	3	306	0	111081
2.w.	Reptiles	6	0	0	0	0	0	1	0	7
2.x.	Amphibians	3151	0	0	0	0	0	80	0	3231
2.y.	Fish	7919	739	280	0	5384	0	516	0	14838
2.z.	TOTAL	236394	107450	50866	80814	39645	8725	7305	0	531199
			100	20000	55011	55510	5.20	. 500	Ū	55.100

TABLE 3: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS

Products versus species

	3.1	3.2	3.3	3.4	3.5	3.6	3.7	3.8	3.9	3.10	3.11
	Species	Products/	Products/	Products/	Products/	Products/	Products/	Products/	Potential or	Other toxico-	Total
	-	substances or	substances	substances	substances	substances	substances	substances	actual contami-	logical or	
		devices for	used or	used or	used or	used or	used or	used or	nants in the	safety	
		human	intended to	intended to	intended to	intended to	intended to be	intended to be	general envi-	evaluations	
		medicine and	be used	be used	be used	be used	used mainly	used mainly	ronment which		
		dentistry and	mainly in	mainly in	mainly in	mainly as	as additives in	as additives in	do not appear in		
		for veterinary	agriculture	industry	the	cosmetics	food for	food for	other columns		
		medicine			household	or toiletries	human	animal			
							consumption	consumption			
3.a.	Mice	2819	92	2382	0	0	322	0	247	252	6114
3.b.	Rats	6140	5574	8389	0	0	1558	479	0	960	23100
3.c.	Guinea-Pigs	276	0	131	0	0	19	0	0	3	429
3.d.	Hamsters	45	0	0	0	0	0	0	0	0	45
3.e.	Other Rodents	0	0	0	0	0	0	0	0	0	0
3.f.	Rabbits	2554	885	371	0	0	6	104	0	0	3920
3.g.	Cats	6	0	0	0	0	0	0	0	0	6
3.h.	Dogs	301	100	0	0	0	0	0	0	0	401
3.i.	Ferrets	0	0	0	0	0	0	0	0	0	0
3.j.	Other Carnivores	0	0	0	0	0	0	0	0	0	0
3.k.	Horses, donkeys and cross breds	0	0	0	0	0	0	0	0	0	0
3.1.	Pigs	0	0	0	0	0	56	0	0	0	56
3.m.	Goats	0	0	0	0	0	0	0	0	0	0
3.n.	Sheep	0	0	0	0	0	0	0	0	0	0
3.o.	Cattle	0	0	0	0	0	0	0	0	0	0
3.p.	Prosimians	0	0	0	0	0	0	0	0	0	0
3.q.	New World Monkeys	14	0	0	0	0	0	0	0	0	14
3.r.	Old World Monkeys	0	0	0	0	0	0	0	0	0	0
3.s.	Apes	0	0	0	0	0	0	0	0	0	0
3.t.	Other Mammals	0	0	0	0	0	0	0	0	0	0
3.u.	Quail	0	152	0	0	0	0	0	0	0	152
3.v.	Other birds	0	24	0	0	0	0	0	0	0	24
3.w.	Reptiles	0	0	0	0	0	0	0	0	0	0
3.x.	Amphibians	0	0	0	0	0	0	0	0	0	0
3.y.	Fish	0	350	180	0	0	0	0	4854	0	5384
3.z.	TOTAL	12155	7177	11453	0	0	1961	583	5101	1215	39645

TABLE 4: NUMBER OF ANIMALS USED IN EXPERIMENTS FOR STUDIES ON HUMAN AND ANIMAL DISEASES

Main categories versus species

	4.1	4.2	4.3	4.4	4.5	4.6	4.7
	Species	Human cardiovascular	Human nervous and	Human cancer (excluding	Other human diseases	Studies specific to animal	Total
		diseases	mental disorders	evaluations of carcinogenic		diseases	
				hazards or risks)			
4.a.	Mice	15137	13750	48651	77344	12479	167361
4.b.	Rats	3922	8641	2910	29959	50	45482
4.c.	Guinea-Pigs	0	24	0	1794	145	1963
4.d.	Hamsters	0	19	125	588	76	808
4.e.	Other Rodents	0	0	0	2781	0	2781
4.f.	Rabbits	340	5	28	1181	212	1766
4.g.	Cats	0	1	0	24	69	94
4.h.	Dogs	68	0	0	52	178	298
4.i.	Ferrets	0	0	0	152	71	223
4.j.	Other Carnivores	0	0	0	0	0	0
4.k.	Horses, donkeys and cross breds	0	0	0	0	165	165
4.1.	Pigs	277	0	21	511	3673	4482
4.m.	Goats	89	0	0	142	2	233
4.n.	Sheep	13	0	0	162	230	405
4.0.	Cattle	0	0	0	61	1265	1326
4.p.	Prosimians	0	0	0	0	0	0
4.q.	New World Monkeys	0	5	0	27	0	32
4.r.	Old World Monkeys	0	0	0	201	0	201
4.s.	Apes	0	0	0	0	0	0
4.t.	Other Mammals	0	0	0	13	0	13
4.u.	Quail	0	0	0	0	0	0
4.v.	Other birds	0	0	0	482	33870	34352
4.w.	Reptiles	0	0	0	0	1	1
4.x.	Amphibians	0	0	7	0	0	7
4.y.	Fish	0	0	0	271	933	1204
4.z.	TOTAL	19846	22445	51742	115745	53419	263197

TABLE 5: NUMBER OF ANIMALS USED IN PRODUCTION AND QUALITY CONTROL OF PRODUCTS AND DEVICES FOR HUMAN MEDICINE AND DENTISTRY AND FOR VETERINARY MEDICINE

Regulatory requirements versus species

		1		equirements versus				
	5.1	5.2	5.3	5.4	5.5	5.6	5.7	5.8
	Species	National legislation	EC legislation	Member Country of Council	Other legislation	Any combination of	No regulatory	Total
	•	specific to a single EC	including European	of Europe (but not EC)		5.2/ 5.3/ 5.4/ 5.5	requirements	
		Member State	Pharmacopoeia	legislation			1	
		1)	(requirements)	2)				
5.a.	Mice	0	11126	0	1768	14929	2803	30626
5.b.	Rats	0	3650	0	72	30483	593	34798
5.c.	Guinea-Pigs	0	1139	7	0	2234	1464	4844
5.d.	Hamsters	0	0	0	0	4354	7	4361
5.e.	Other Rodents	0	0	0	0	0	0	0
5.f.	Rabbits	0	34	0	0	1996	280	2310
5.g.	Cats	0	13	0	0	52	18	83
5.h.	Dogs	0	0	0	0	149	138	287
5.i.	Ferrets	0	0	0	0	0	0	0
5.j.	Other Carnivores	0	0	0	0	0	0	0
5.k.	Horses, donkeys and cross breds	0	0	0	0	136	1402	1538
5.1.	Pigs	0	127	0	9	1248	423	1807
5.m.	Goats	0	0	0	0	0	0	0
5.n.	Sheep	8	0	0	0	26	2219	2253
5.o.	Cattle	7	0	26	10	161	171	375
5.p.	Prosimians	0	0	0	0	0	0	0
5.q.	New World Monkeys	0	0	0	0	0	0	0
5.r.	Old World Monkeys	0	0	0	0	0	10	10
5.s.	Apes	0	0	0	0	0	0	0
5.t.	Other Mammals	0	0	0	0	0	0	0
5.u.	Quail	0	0	0	0	0	0	0
5.v.	Other birds	40	0	0	0	37024	11044	48108
5.w.	Reptiles	0	0	0	0	0	0	0
5.x.	Amphibians	0	0	0	0	0	0	0
5.y.	Fish	0	0	0	0	0	280	280
5.z.	TOTAL	55	16089	33	1859	92792	20852	131680

Examples:

Footnotes:

5.2 – France is testing due to a UK (or FR) specific requirement

5.3 - UK is testing according to EC legislation

5.4 – Spain is testing due to a Hungarian requirement

5.5 – Sweden is testing due to a US specific requirement

5.6 - Germany is testing due to a Czech requirement (also an EC

requirement)

Note: columns 5.2 - 5.5 refer to the legislation imposing that the test be carried out and

not to the body which has issued the actual test method, guideline or protocol.

Example: a test required by French legislation and carried out in Belgium according to an

 $ISO\ protocol\ must\ be\ coded\ as\ a\ national\ (FR)\ legislative\ requirement\ and\ be$

entered into column 5.2 in the tables submitted by Belgium.

- 1) EC Member States: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden, United Kingdom
- 2) Member Countries of Council of Europe (non-EC): Albania, Andorra, Bulgaria, Croatia, Cyprus, Czech Rep., Estonia, Hungary, Iceland, Latvia, Liechtenstein, Lithuania, Malta, Moldova, Norway, Poland, Romania, Russia, San Marino, Slovakia, Slovenia, Switzerland, 'the former Yugoslav Rep. of Macedonia', Turkey, Ukraine

NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS

Regulatory requirements versus species

	6.1	6.2	6.3	6.4	6.5	6.6	6.7	6.8
	Species	National legislation	EC legislation	Member Country of Council	Other legislation	Any combination of	No regulatory	Total
	-	specific to a single EC	including European	of Europe (but not EC)	-	6.2/ 6.3/ 6.4/ 6.5	requirements	
		Member State	Pharmacopoeia	legislation				
		1)	(requirements)	2)				
6.a.	Mice	0	0	0	84	4125	1905	6114
6.b.	Rats	86	0	0	272	21161	1581	23100
6.c.	Guinea-Pigs	0	0	0	0	400	29	429
6.d.	Hamsters	0	0	0	0	45	0	45
6.e.	Other Rodents	0	0	0	0	0	0	0
6.f.	Rabbits	0	0	0	0	3914	6	3920
6.g.	Cats	0	0	0	6	0	0	6
6.h.	Dogs	0	0	0	0	401	0	401
6.i.	Ferrets	0	0	0	0	0	0	0
6.j.	Other Carnivores	0	0	0	0	0	0	0
6.k.	Horses, donkeys and cross breds	0	0	0	0	0	0	0
6.1.	Pigs	0	0	0	0	56	0	56
6.m.	Goats	0	0	0	0	0	0	0
6.n.	Sheep	0	0	0	0	0	0	0
6.0.	Cattle	0	0	0	0	0	0	0
6.p.	Prosimians	0	0	0	0	0	0	0
6.q.	New World Monkeys	0	0	0	0	0	14	14
6.r.	Old World Monkeys	0	0	0	0	0	0	0
6.s.	Apes	0	0	0	0	0	0	0
6.t.	Other Mammals	0	0	0	0	0	0	0
6.u.	Quail	0	0	0	0	152	0	152
6.v.	Other birds	0	0	0	0	0	24	24
6.w.	Reptiles	0	0	0	0	0	0	0
6.x.	Amphibians	0	0	0	0	0	0	0
6.y.	Fish	321	0	0	0	3830	1233	5384
6.z.	TOTAL	407	0	0	362	34084	4792	39645

Examples:

6.2 – France is testing due to a UK (or FR) specific requirement

6.3 - UK is testing according to EC legislation

6.4 – Spain is testing due to a Hungarian requirement

6.5 – Sweden is testing due to a US specific requirement

6.6 - Germany is testing due to a Czech requirement (also an EC requirement)

Note: columns 6.2 - 6.5 refer to the legislation imposing that the test be carried out and

not to the body which has issued the actual test method, guideline or protocol.

a test required by French legislation and carried out in Belgium according to an ISO protocol must be coded as a national (FR) legislative requirement and be

entered into column 6.2 in the tables submitted by Belgium.

Footnotes:

EC Member States: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden, United Kingdom

Member Countries of Council of Europe (non-EC): Albania, Andorra, Bulgaria, Croatia, Cyprus, Czech Rep., Estonia, Hungary, Iceland, Latvia, Liechtenstein, Lithuania, Malta, Moldova, Norway, Poland, Romania, Russia, San Marino, Slovakia, Slovenia, Switzerland, 'the former Yugoslav Rep. of Macedonia', Turkey, Ukraine

Example:

TABLE 7: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS

Types of tests versus species

	7.1 Species		7.2 ab-acute toxicity to (including limit to		7.3 Skin irritation	7.4 Skin sensitisatio	7.5 Eye irritation	7.6 Sub- chronic and	7.7 Carcino- genicity	7.8 Develop- mental	7.9 Muta- genicit	7.10 Repro- ductive	7.11 Toxicity to aquatic	7.12 Other	7.13 Total
			(v.uug			n		chronic toxicity	gomony	toxicity	у	toxicity	vertebra- tes not included in other		
		7.2.1. LD50, LC50	7.2.2 Other lethal methods	7.2.3 Non lethal clinical signs methods									columns		
7.a.	Mice	0	10	839	0	2077	0	134	236	0	2435	0	0	383	6114
7.b.	Rats	0	1009	3818	611	0	0	3242	0	6661	471	4852	0	2436	23100
7.c.	Guinea-Pigs	0	0	18	0	290	0	23	0	0	0	0	0	98	429
7.d.	Hamsters	0	0	45	0	0	0	0	0	0	0	0	0	0	45
7.e.	Other Rodents	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.f.	Rabbits	0	0	140	330	0	167	24	0	60	0	1719	0	1480	3920
7.g.	Cats	0	0	6	0	0	0	0	0	0	0	0	0	0	6
7.h.	Dogs	0	0	169	0	0	0	224	0	0	0	0	0	8	401
7.i.	Ferrets	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.j.	Other Carnivores	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.k.	Horses, donkeys and cross breds	_				_	_		_						_
7.1.	Pigs	0	0	0	0	0	0	56	0	0	0	0	0	0	56
7.m.	Goats	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.n.	Sheep	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.o.	Cattle	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.p.	Prosimians	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.q.	New World Monkeys	0	0	0	0	0	0	0	0	0	0	0	0	14	14
7.r.	Old World Monkeys	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.s.	Apes	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.t.	Other Mammals	0	0	0	0	0	0	0		0	0	0	0	0	0
7.u.	Quail	152	0	0	0	0	0	0	0	0	0	0	0	0	152
7.v.	Other birds	0	0	0	0	0	0	0	0	0	0	0	0	24	24
7.w.	Reptiles	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.x.	Amphibians	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.y.	Fish	1278	535	1713	0	0	0	790	0	804	0	0	264	0	5384
7.z.	TOTAL	1430	1554	6748	941	2367	167	4493	236	7525	2906	6571	264	4443	39645

TABLE 8: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS

Types of tests versus products

	8.1 Products		8.2 nd sub-acute tox ods (including li		8.3 Skin irritation	8.4 Skin sensitisatio n	8.5 Eye irritation	8.6 Sub- chronic and chronic toxicity	8.7 Carcino genicity	8.8 Develop- mental toxicity	8.9 Muta- genicit y	8.10 Reproductive toxicity	8.11 Toxicity to aquatic vertebra- tes not included	8.12 Other	8.13 Total
		8.2.1. LD50, LC50	8.2.2 Other lethal methods	8.2.3 Non lethal clinical signs methods									in other columns		
8.a.	Products/substances or devices for human medicine and dentistry and for veterinary medicine	0	119	3200	228	419	6	1469	0	1275	1600	961	0	2878	12155
8.b.	Products/substances used or intended to be used mainly in agriculture	152	74	6	57	66	12	446	0	5338	26	843	0	157	7177
8.c.	Products/substances used or intended to be used mainly in industry	144	826	1761	653	1759	146	864	0	108	830	4179	0	183	11453
8.d.	Products/substances used or intended to be used mainly in the household	0	0	0	0	0	0	0	0	0	0	0	0	0	0
8.e.	Products/substances used or intended to be used mainly as cosmetics or toiletries	0	0	0	0	0	0	0	0	0	0	0	0	0	0
8.f.	Products/substances used or intended to be used mainly as additives in food for human consumption	0	0	68	3	79	3	1150	0	0	231	165	0	262	1961
8.g.	Products/substances used or intended to be used mainly as additives in food for animal consumption	0	0	0	0	0	0	160	0	0	0	423	0	0	583
8.h.	Potential or actual contaminants in the general environment which do not appear in other columns	1 134	535	1713	0	0	0	404	28	804	219	0	264	0	5101
8.i.	Other toxicological or safety evaluations	0	0	0	0	44	0	0	208	0	0	0	0	963	1215
8.j.	TOTAL	1430	1554	6748	941	2367	167	4493	236	7525	2906	6571	264	4443	39645

POLAND

Statistical data submitted

The statistical data have been submitted by the Ministry of Science and Higher Education, Department of Scientific Research.

Comments of the Polish authorities

In accordance with Directive 86/609/EEC regarding the protection of animals used for experimental and other scientific purposes, animal experiments in Poland are regulated by the Experiments on Animals Act (Act of 21 January 2005 on experiments on live animals, Dz.U. Nr 33, poz. 289). The Minister of Science and Higher Education is responsible for enforcing the act.

Every animal experiment to be performed has to be recommended by a recognized ethical review committee (Local Commission for Ethics in Animal Experiments (LKE)). At the moment 18 ethical review committees are recognized. They are supervised by National Commission for Ethics in Animal Experiments (KKE). Members of KKE and LKE are independent on public administration institutions and user establishments. Licenses to perform animal experiments in individual user establishments are issued by the Minister of Science and Higher Education after receiving positive National Commission's (KKE) opinion.

The data on the use of experimental animals in Poland in 2005 was collected for the first time, so the number of animals used cannot be compared with the figures for the preceding years. The data collected comply with the procedure agreed by the Member States and the Commission of the European Communities pursuant to Article 26 of Directive 86/609/EEC.

The total number of animals used in experiments in Poland in 2005 was 358,829.

No animals were re-used.

Rodents accounted for 56,6% of all animals used – 202,983 animals.

No primates were used.

Cold-blooded animals (fish and amphibians) represented 15,7% of the animals used – 56,292 animals.

For the species which should be obtained from registered breeding or supplying establishments within Poland, over 95% of animals listed were so sourced and less than 4,5% were sourced outside of EC or Council of Europe member countries.

53,23 % of the animals were used in biological studies.

31,67 % of the animals were used in the research, development, production and quality control of products and devices for human medicine, dentistry and veterinary medicine.

6,18 % of the animals were used in toxicological studies.

8,93 % of the animals were used for diagnosis of disease, education and other purposes.

No animals were used in the testing of cosmetics products. Using animals for the purpose of testing of cosmetics products is prohibited by Polish law.

Poland was also asked to provide some feed back to the following specific question:

Question: Could PL provide some background information which could **explain the reasons** for the significant use of other carnivores, other mammals, cattle, other rodents, quails, horses etc., pigs and other birds in comparison to other Member States?

Almost 80% of 'other rodents' used for experiments in Poland are conducted at one of the largest academic centres, which collaborates with international universities and research institutes. Many experiments within the framework of international research projects are performed in Poland. It is important to emphasize that these research studies chiefly concern environmental research and the procedures used in these studies have the lowest level of invasiveness. The other 20% are used for environmental research much of which is unique to Poland and Central Europe.

Other carnivores are used in environmental studies, the study of endangered species and the process of re-introducing indigenous species to Poland (eg, wolves, bears etc).

The number of horses, donkeys and crossbreeds used in experiments is higher than in other Member States due to the Polish tradition of horse-breeding. These include studying new breeding programmes, assessment of transport conditions and nutrition, for example.

Poland produces a large amount of pork, beef and milk, therefore scientific research on pigs and cows is undertaken to maintain and improve the quality of these products.

Use of other mammals is necessary because agriculture is a big industry in Poland and animal testing is needed to monitor the effects of modern farming on the environment. These experiments involve mainly boars, bats and European bison.

Quails are used for toxicology tests for national as well as European companies. Other birds are also used for toxicological tests of pharmacological substances (required by Polish law), and ecological field studies on bird populations and the influence of agriculture on the bird population.

TABLE 1: NUMBER OF ANIMALS USED IN RELATION TO THEIR PLACE OF ORIGIN

Origin versus species

1.1	1.2	1.3	1.4	1.5	1.6	1.7
Species	Total	Animals coming from registered	Animals coming from	Animals coming from	Animals coming from	Re-used animals
		breeding or supplying	elsewhere in the EC	Member Countries of the	other origins	
		establishments within the reporting		Council of Europe which are		
		country		parties to the Convention ETS 123 (excluding EC Member		
				States)		
1.a. Mice (Mus musculus)	126492	119158	2772	790	3772	
1.b. Rats (Rattus norvegicus)	51558	50988	0	32	538	
1.c. Guinea-Pigs (Cavia porcellus)	10763	10731	0	0	32	
1.d. Hamsters (Mesocricetus)	243	194	0	0	49	
1.e. Other Rodents (other <i>Rodentia</i>)	10826					
1.f. Rabbits (Oryctolagus cuniculus)	3101	2879	0	0	222	0
1.g. Cats (Felis catus)	121	67	0	0	54	0
1.h. Dogs (Canis familiaris)	618	419	0	0	199	0
1.i. Ferrets (Mustela putorius furo)	19	14	0	0	5	0
1.j. Other Carnivores (other <i>Carnivora</i>)	6970					
1.k. Horses, donkeys and cross breds (<i>Equidae</i>)	681					
1.l. Pigs (<i>Sus</i>)	7358					
1.m. Goats (Capra)	130					
1.n. Sheep (Ovis)	2023					
1.o. Cattle (<i>Bos</i>)	13834					
1.p. Prosimians (<i>Prosimia</i>)	0	0	0	0	0	0
1.q. New World Monkeys (Ceboidea)	0	0	0	0	0	0
1.r. Old World Monkeys (Cercopithecoidea)	0	0	0	0	0	0
1.s. Apes (Hominoidea)	0	0	0	0	0	0
1.t. Other Mammals (other <i>Mammalia</i>)	5061					
1.u. Quail (Coturnix coturnix)	1470	1470	0	0	0	
1.v. Other birds (other <i>Aves</i>)	61148					
1.w. Reptiles (Reptilia)	121					
1.x. Amphibians (Amphibia)	13216					
1.y. Fish (<i>Pisces</i>)	43076					
1.z. TOTAL	358829					

Note 1: Column 1.5 concerns only those Member Countries of the Council of Europe which, at the beginning of the reporting period, are Parties to the Convention ETS 123. Thus an updated list of those countries has to be used when filling in this column.

Note 2: Only the white boxes need to be completed.

Note 3: The number of re-used animals in column 1.7 should be excluded from the total in the column 1.2

TABLE 2: NUMBER OF ANIMALS USED IN EXPERIMENTS FOR SELECTED PURPOSES

Purpose versus species

	2.1	2.2	2.3	2.4	2.5	2.6	2.7	2.8	2.9	2.10
	Species	Biological	Research and	Production and	Production and	Toxicological	Diagnosis of	Education and	Other	Total
		studies of a	development of	quality control of	quality control of	and other safety	disease	training		
		fundamenta	products and	products and	products and	evaluations				
		l nature	devices for human	devices for	devices for	(including				
			medicine and	human medicine	veterinary	safety				
			dentistry and for	and dentistry	medicine	evaluation of				
			veterinary medicine			products and				
			(excluding			devices for human				
			toxicological and			medicine and				
			other safety			dentistry and				
			evaluations			for veterinary				
			counted in column			medicine)				
			2.6)			,				
2.a.	Mice	45285	28377	20196	3676	13370	14217	860	511	126492
2.b.	Rats	33154	4018	5754	105	3709	3877	767	174	51558
2.c.	Guinea-Pigs	579	0	7158	996	1557	444	21	8	10763
2.d.	Hamsters	138	31	0	0	0	70	4	0	243
2.e.	Other Rodents	10250	0	0	0	356	20	34	166	10826
2.f.	Rabbits	754	68	1174	439	147	233	72	214	3101
2.g.	Cats	24	0	45	50	0	0	2	0	121
2.h.	Dogs	319	9	0	21	29	133	77	30	618
2.i.	Ferrets	5	0	0	14	0	0	0	0	19
2.j.	Other Carnivores	6970	0	0	0	0	0	0	0	6970
2.k.	Horses, donkeys and cross breds	611	0	0	0	5	30	35	0	681
2.1.	Pigs	6978	8	0	0	20	13	19	320	7358
2.m.	Goats	60	6	0	0	0	36	27	1	130
2.n.	Sheep	1796	61	0	0	72	0	63	31	2023
2.o.	Cattle	12969	40	0	41	88	48	53	595	13834
2.p.	Prosimians	0	0	0	0	0	0	0	0	0
2.q.	New World Monkeys	0	0	0	0	0	0	0	0	0
2.r.	Old World Monkeys	0	0	0	0	0	0	0	0	0
2.s.	Apes	0	0	0	0	0	0	0	0	0
2.t.	Other Mammals	5058	0	0	0	0	0	3	0	5061
2.u.	Quail	1033	0	0	0	372	0	65	0	1470
2.v.	Other birds	17194	40126	472	758	120	302	529	1647	61148
2.w.	Reptiles	80	0	0	0	0	0	41	0	121
2.x.	Amphibians	12200	0	0	0	0	0	1016	0	13216
2.y.	Fish	35536	0	0	0	2315	300	515	4410	43076
2.z.	TOTAL	190993	72744	34799	6100	22160	19723	4203	8107	358829

TABLE 3: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS

Products versus species

	3.1	3.2	3.3	3.4	3.5	3.6	3.7	3.8	3.9	3.10	3.11
	Species	Products/	Products/	Products/	Products/	Products/	Products/	Products/	Potential or	Other toxico-	Total
		substances or	substances	substances	substances	substances	substances	substances	actual contami-	logical or	
		devices for	used or	used or	used or	used or	used or	used or	nants in the	safety	
		human	intended to	intended to	intended to	intended to	intended to be	intended to be	general envi-	evaluations	
		medicine and	be used	be used	be used	be used	used mainly	used mainly	ronment which		
		dentistry and	mainly in	mainly in	mainly in	mainly as	as additives in	as additives in	do not appear in		
		for veterinary	agriculture	industry	the	cosmetics	food for	food for	other columns		
		medicine			household	or toiletries	human	animal			
							consumption	consumption			
3.a.	Mice	9186	24				40		100	4020	13370
3.b.	Rats	1450	460	665	31				128	975	3709
3.c.	Guinea-Pigs	1459	98								1557
3.d.	Hamsters										0
3.e.	Other Rodents		28	28					300		356
3.f.	Rabbits	126	9	6	6						147
3.g.	Cats										0
3.h.	Dogs								29		29
3.i.	Ferrets										0
3.j.	Other Carnivores										0
3.k.	Horses, donkeys and cross breds		5								5
3.1.	Pigs						20				20
3.m.	Goats										0
3.n.	Sheep								72		72
3.o.	Cattle	8						80			88
3.p.	Prosimians										0
3.q.	New World Monkeys										0
3.r.	Old World Monkeys										0
3.s.	Apes										0
3.t.	Other Mammals										0
3.u.	Ouail		372								372
3.v.	Other birds							120			120
3.w.	Reptiles							. = 0			0
3.x.	Amphibians										0
3.y.	Fish	200	2079						36		2315
3.z.	TOTAL	12429	3075	699	37	0	60	200	665	4995	22160

TABLE 4: NUMBER OF ANIMALS USED IN EXPERIMENTS FOR STUDIES ON HUMAN AND ANIMAL DISEASES

Main categories versus species

	4.1	4.2	4.3	4.4	4.5	4.6	4.7
	Species	Human cardiovascular	Human nervous and	Human cancer (excluding	Other human diseases	Studies specific to animal	Total
		diseases	mental disorders	evaluations of carcinogenic		diseases	
				hazards or risks)			
	Mice	2924	37604	7473	10829	3546	62376
4.b.	Rats	3110	16646	550	6604	86	26996
4.c.	Guinea-Pigs		4			444	448
4.d.	Hamsters				70		70
4.e.	Other Rodents		389		20		409
4.f.	Rabbits	60		5	228		293
4.g.	Cats				18	9	27
4.h.	Dogs			9		148	157
4.i.	Ferrets						0
	Other Carnivores					35	35
4.k.	Horses, donkeys and cross breds	8				36	44
4.1.	Pigs	45				40	85
4.m.	Goats					5	5
4.n.	Sheep	4			21	42	67
4.0.	Cattle					135	135
	Prosimians						0
4.q.	New World Monkeys						0
4.r.	Old World Monkeys						0
4.s.	Apes						0
4.t.	Other Mammals						0
4.u.	Quail						0
4.v.	Other birds		-		152	490	642
4.w.	Reptiles				·		0
4.x.	Amphibians				_		0
	Fish					500	500
4.z.	TOTAL	6151	54643	8037	17942	5516	92289

TABLE 5: NUMBER OF ANIMALS USED IN PRODUCTION AND QUALITY CONTROL OF PRODUCTS AND DEVICES FOR HUMAN MEDICINE AND DENTISTRY AND FOR VETERINARY MEDICINE

Regulatory requirements versus species

	5.1	5.2	5.3	5.4	5.5	5.6	5.7	5.8
	Species	National legislation	EC legislation	Member Country of Council	Other legislation	Any combination of	No regulatory	Total
		specific to a single EC	including European	of Europe (but not EC)		5.2/ 5.3/ 5.4/ 5.5	requirements	
		Member State	Pharmacopoeia	legislation				
		1)	(requirements)	2)				
5.a.	Mice	7474	8615		705	2398	4680	23872
5.b.	Rats		5412		129	318		5859
5.c.	Guinea-Pigs	1408	5813		20	10	903	8154
5.d.	Hamsters							0
5.e.	Other Rodents							0
5.f.	Rabbits	596	300		16	501	200	1613
5.g.	Cats	76	11			8		95
5.h.	Dogs	21						21
5.i.	Ferrets	14						14
5.j.	Other Carnivores							0
5.k.	Horses, donkeys and cross breds							0
5.1.	Pigs							0
5.m.	Goats							0
5.n.	Sheep							0
5.o.	Cattle		41					41
5.p.	Prosimians							0
5.q.	New World Monkeys							0
5.r.	Old World Monkeys							0
5.s.	Apes							0
5.t.	Other Mammals							0
5.u.	Quail							0
5.v.	Other birds	1230						1230
5.w.	Reptiles							0
5.x.	Amphibians							0
5.y.	Fish							0
5.z.	TOTAL	10819	20192	0	870	3235	5783	40899

Examples:

5.2 – France is testing due to a UK (or FR) specific requirement

5.3 - UK is testing according to EC legislation

5.4 – Spain is testing due to a Hungarian requirement

5.5 – Sweden is testing due to a US specific requirement

5.6 - Germany is testing due to a Czech requirement (also an EC requirement)

Note: Example:

columns 5.2 - 5.5 refer to the legislation imposing that the test be carried out and not to the body which has issued the actual test method, guideline or protocol.

a test required by French legislation and carried out in Belgium according to an

ISO protocol must be coded as a national (FR) legislative requirement and be

entered into column 5.2 in the tables submitted by Belgium.

Footnotes:

EC Member States: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden, United Kingdom

Member Countries of Council of Europe (non-EC): Albania, Andorra, Bulgaria, Croatia, Cyprus, Czech Rep., Estonia, Hungary, Iceland, Latvia, Liechtenstein, Lithuania, Malta, Moldova, Norway, Poland, Romania, Russia, San Marino, Slovakia, Slovenia, Switzerland, 'the former Yugoslav Rep. of Macedonia', Turkey, Ukraine

NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS TABLE 6:

Regulatory requirements versus species

	6.1	6.2	6.3	6.4	6.5	6.6	6.7	6.8
	Species	National legislation	EC legislation	Member Country of Council	Other legislation	Any combination of	No regulatory	Total
	-	specific to a single EC	including European	of Europe (but not EC)		6.2/ 6.3/ 6.4/ 6.5	requirements	
		Member State	Pharmacopoeia	legislation			-	
		1)	(requirements)	2)				
6.a.	Mice	3818	8290		20		1242	13370
6.b.	Rats	1836	1357				516	3709
6.c.	Guinea-Pigs		1557					1557
6.d.	Hamsters							0
6.e.	Other Rodents						356	356
6.f.	Rabbits		147					147
6.g.	Cats							0
6.h.	Dogs		29					29
6.i.	Ferrets							0
6.j.	Other Carnivores							0
6.k.	Horses, donkeys and cross breds		5					5
6.1.	Pigs						20	20
6.m.	Goats							0
6.n.	Sheep						72	72
6.0.	Cattle	8					80	88
6.p.	Prosimians							0
6.q.	New World Monkeys							0
6.r.	Old World Monkeys							0
6.s.	Apes							0
6.t.	Other Mammals							0
6.u.	Quail		372					372
6.v.	Other birds						120	120
6.w.	Reptiles							0
6.x.	Amphibians							0
6.y.	Fish		2279				36	2315
6.z.	TOTAL	5662	14036	0	20	0	2442	22160

Examples:

Footnotes:

6.2 – France is testing due to a UK (or FR) specific requirement

6.3 - UK is testing according to EC legislation

6.4 – Spain is testing due to a Hungarian requirement

6.5 – Sweden is testing due to a US specific requirement

6.6 - Germany is testing due to a Czech requirement (also an EC

requirement)

Note: columns 6.2 - 6.5 refer to the legislation imposing that the test be carried out and

not to the body which has issued the actual test method, guideline or protocol.

Example: a test required by French legislation and carried out in Belgium according to an

ISO protocol must be coded as a national (FR) legislative requirement and be

entered into column 6.2 in the tables submitted by Belgium.

EC Member States: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden, United Kingdom

Member Countries of Council of Europe (non-EC): Albania, Andorra, Bulgaria, Croatia, Cyprus, Czech Rep., Estonia, Hungary, Iceland, Latvia, Liechtenstein, Lithuania, Malta, Moldova, Norway, Poland, Romania, Russia, San Marino, Slovakia, Slovenia, Switzerland, 'the former Yugoslav Rep. of Macedonia', Turkey, Ukraine

TABLE 7: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS

Types of tests versus species

	7.1		7.2		7.3	7.4	7.5	7.6	7.7	7.8	7.9	7.10	7.11	7.12	7.13
	Species		ub-acute toxicity t		Skin	Skin	Eye	Sub-	Carcinog	Develop-	Muta-	Repro-	Toxicity	Other	Total
			(including limit to	est)	irritation	sensitisatio	irritation	chronic and	enicity	mental	genicit	ductive	to aquatic		,
						n		chronic		toxicity	У	toxicity	vertebra-		,
								toxicity					tes not included		
													in other		
													columns		
		7.2.1.	7.2.2	7.2.3											
		LD50,	Other lethal	Non lethal											
		LC50	methods	clinical signs											
				methods											
7.a.	Mice	306	7370	152				364						5178	13370
7.b.	Rats	165		385				1651		316		371		821	3709
7.c.	Guinea-Pigs		420	756	60	313								8	1557
7.d.	Hamsters							000							0
7.e.	Other Rodents	56			70		00	300						00	356
7.f.	Rabbits				72		36							39	147
7.g.	Cats											29			0 29
7.h. 7.i.	Dogs Ferrets											29			0
7.i.	Other Carnivores														0
7.J. 7.k.	Horses, donkeys and cross													5	5
/ .K.	breds													3	
7.1.	Pigs													20	20
7.m.	Goats														0
7.n.	Sheep									35		37			72
7.o.	Cattle													88	88
7.p.	Prosimians														0
7.q.	New World Monkeys														0
7.r.	Old World Monkeys														0
7.s.	Apes														0
7.t.	Other Mammals														0
7.u.	Quail	180										192			372
7.v.	Other birds													120	120
7.w.	Reptiles														0
7.x.	Amphibians														0
7.y.	Fish	2179										36	100		2315
7.z.	TOTAL	2886	7790	1293	132	313	36	2315	0	351	0	665	100	6279	22160

TABLE 8: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS

Types of tests versus products

	8.1		8.2		8.3	8.4	8.5	8.6	8.7	8.8	8.9	8.10	8.11	8.12	8.13
	Products	meth	nd sub-acute tox ods (including li	mit test)	Skin irritation	Skin sensitisatio n	Eye irritation	Sub- chronic and chronic toxicity	Carcinog enicity	Develop- mental toxicity	Muta- genicit y	Repro- ductive toxicity	Toxicity to aquatic vertebra- tes not included in other columns	Other	Total
		8.2.1. LD50, LC50	8.2.2 Other lethal methods	8.2.3 Non lethal clinical signs methods											
8.a.	Products/substances or devices for human medicine and dentistry and for veterinary medicine	531	7750	946	123	215	24	711		316			100	1713	12429
8.b.	Products/substances used or intended to be used mainly in agriculture	2302		21	3	98	6	224				416		5	3075
8.c.	Products/substances used or intended to be used mainly in industry	33		315	3		3	198				147			699
8.d.	Products/substances used or intended to be used mainly in the household	20		11	3		3								37
8.e.	Products/substances used or intended to be used mainly as cosmetics or toiletries														0
8.f.	Products/substances used or intended to be used mainly as additives in food for human consumption		40											20	60
8.g.	Products/substances used or intended to be used mainly as additives in food for animal consumption													200	200
8.h.	Potential or actual contaminants in the general environment which do not appear in other columns							528		35		102			665
8.i.	Other toxicological or safety evaluations							654						4341	4995
8.j.	TOTAL	2886	7790	1293	132	313	36	2315	0	351	0	665	100	6279	22160

PORTUGAL

Statistical data submitted

The statistical data have been submitted by the "Ministério da Agricultura, Desenvolvimento Rural e das Pescas – Direcção Geral de Veterinária" (Ministry of Agriculture, Rural Development and Fisheries – General Direction of Veterinary – Directorate for Animal Medicines and Products, Animal Welfare and Feed)

Comments of Portuguese authorities

1. Total number of animals used by species

In 2005, the total number of animals used for experimental and other scientific purposes in Portugal was 41621.

Compared to the data of 2002, where the total number of used animals was 44577, it means that with regard to 2005 it was a slight decrease on the use of animals of 6,6%.

As in the previous report, Mice are the most commonly used species representing 68,04% of the total number of animals.

The second most used group of animals was Rats (16,32%), the third is represented by the cold-blooded animals (11,53%) and the fourth by the rabbits with 1,43%. The group of Artio and Perissodactyla represent 1,11% of the total number of animals used and Carnivors represent only 0,09%.

Rodents with rabbits represent 87,01% of the total number of animals used.

As in other previous reports, in Portugal, non-human primates were not used.

Comparison with the data of the previous report (data of 2002)

The percentages of classes of animals used in 2002 (44577 animals) and in 2005 (41621 animals) are represented in the following table:

Class of animals (%)	2002	2005
Mice	62	68,04
Rats	27,6	16,32
Guinea-pigs	1,42	0,91
Hamsters and other rodents	0,21	0,31
Rabbits	2,04	1,43
Cold-blooded animals	5,38	11,53

Quail and other birds	0,44	0,27
Artio Perissodactyla	0,88	1,11
Carnivors	0,08	0,09

Looking at the data by groups of species, the two major increases that happened in 2005 are in the use of Cold-blooded animals and of Mice.

On the other hand, the biggest decrease was in the use of Rats.

The percentage of Rabbits decreased in 2005 but the percentage of Hamsters slightly increased.

Among the group of the Cold-blooded animals, the general increase was due to the increase on the use of Fish, as the numbers of Reptiles and Amphibians both decreased.

The use of Birds decreased too and this decrease was due to the reduction on the use of Quail but also on Other Birds too.

The use of Artio and Perisodactyla animals increased in 2005. The species that its use decreased among this group was only Goats but all the others increased.

2. Number of animals used by purposes of experiments

In 2005, the percentage of animals (total 41621) used by purposes of experiments was the following:

78,78% of animals were used in Fundamental biology;

6,78% in Research and development for human medicine, veterinary medicine, dentistry;

5,09% in Production and quality control of products and devices in human medicine and dentistry (1,72%) and veterinary medicine (3,37%);

3,02% in Education and training;

2,68% in Diagnosis of disease;

2,26% in Toxicological and other safety evaluation;

1,39% in Other purposes;

Referring to the use of species versus experimental purposes, the highest amount of use of Mice and of Rats is in Fundamental biology and in Research and development for human medicine, veterinary medicine, dentistry.

Comparison with the data of the previous report (data of 2002).

The most significant increase in 2005 is the number of animals that were used for Fundamental biology, which increased from 64,11% in 2002, to 78,78% in 2005.

The other increase that occurred was in the percentage of animals used in Production and quality control of products and devices in human medicine and dentistry, which increased from 0.8% in 2002, to 1.72% in 2005.

The use of animals in the rest of the other categories decreased, for example:

The percentage of animals used for Toxicological and other safety evaluation decreased from 2,92% to 2,26% (from 1301 to 939 animals);

The percentage of animals used for Education and training decreased from 4,78% to 3,02% (from 2132 to 1258 animals);

The percentage of animals used for Other purposes decreased from 2,41% to 1,39% (from 1075 to 577 animals)

1. Number of animals used for Toxicological and safety evaluation by type of products

In 2005, the use of animals in Toxicological and other safety evaluation represents only 2,26%, which only refers to 939 animals, of a total of 41621 animals that were used for experimental purposes in Portugal.

Products or devices for human medicine and dentistry and for veterinary medicine represents 52,08% of the animal used for Toxicological and other safety evaluation; Potential or actual contaminants in the general environment which do not appear in other columns represents 21,30% and Other toxicological or safety evaluations represent 26,62%.

Comparison with the data of the previous report (data of 2002).

Compared to the data of 2002, in 2005 there was a decrease on the use of animals in Toxicological and other safety evaluation. The percentage of animals used for Toxicological and other safety evaluation decreased from 2,92% to 2,26% (from 1301 to 939 animals).

The data of 2002 refers to the same category of products that were tested in 2005.

Products or devices for human medicine and dentistry and for veterinary medicine represented, in 2002, 20,67% of the animal used for Toxicological and other safety evaluation; Potential or actual contaminants in the general environment which do not appear in other columns represented 12,45% and Other toxicological or safety evaluations represent 66,88%.

As in 2002, in 2005 the other groups of products/substances were not tested which means that, for example, there were no animals used for the purpose of evaluating the safety of Cosmetics or Additives in food for animal consumption.

In Portugal, in 2005, there happened a decrease in the number of animals used for Other toxicological or safety evaluation compared to 2002. In 2002, the number of animals used were 870 (66,88%) and in 2005, 250 (26,62%).

2. Number of animals used for the study of diseases

In 2005, the number of animals used for the Studies on humans and animals diseases was 19372, which represents 46,54% of the total number of animals (41621 animals) that were used.

The percentages of animals per type of diseases were:

- 3,28% in Human cardiovascular diseases;
- 24,89% in Human nervous and mental disorders;
- 2,28% in Human cancer (excl. evaluation of carcino hazards);
- 68,15% in Other human diseases;
- 1,40% in Specific animal diseases.

The percentage of the number of animals used for studies of human diseases represents 98,6% (19101 animals) of the total number of animals used for all studies of diseases (19372 animals).

In 2005, the number of animals used to study animal diseases was only 271 (1,40%) while in 2002, that number had been 1922, which means that in 2005, there was a decrease on the use of animals for the study of animal diseases.

In general terms, the proportion of animals used for the studies of diseases showed a slight change when compared to the 2002 data.

In 2005, Cold-blooded animals were not used to study any diseases

3. Number of animals used for Toxicological and other safety evaluations by the types of tests

As pointed out earlier, in 2005, the use of animals in Toxicological and other safety evaluation represents only 2,26%, which only refers to 939 animals, of a total of 41621 animals that were used for experimental purposes in Portugal.

Comparison with the data of the previous report (data of 2002).

The percentages of animals used in toxicity tests for Toxicological and other safety evaluation in 2002 (1301 animals) and in 2005 (939 animals) are represented in the following table:

Type of tests (%)	2002	2005
Acute and sub-acute toxicity testing methods (including limit test)	14,37	37,6
Irritation/sensitization tests	6,53	27,8
Sub-chronic and chronic toxicity	0	0
Mutagenicity and carcinogenicity	8,84	32
Reproductive and developmental toxicity	49,19	0

Toxicity of aquatic vertebrates not included in other columns	0	0
Other	21,1	2,7

In 2005, the biggest percentage of use of animals is due to acute and sub-acute toxicity, which represents 37,6% and means that there was an increase of this type of tests related to the previous report (data 2002).

The use of animals used for Reproductive and developmental toxicity tests decreased from 49,19% in 2002, to 0% in 2005.

Contrary to what happened for the 25 Member States, the use of animals in 2005 for "Other tests" decreased from 21,1% in 2002, to 2,7% in 2005.

4. Type of toxicity tests carried out for Toxicological and other safety evaluations of products

As pointed out earlier, in 2005, the use of animals in Toxicological and other safety evaluation represents only 2,26%, which only refers to 939 animals, of a total of 41621 animals that were used for experimental purposes in Portugal.

Comparison with the data of the previous report (data of 2002)

The numbers of animals used for Toxicological and other safety evaluation per types of products in 2002 (1301 animals) and in 2005 (939 animals) are represented in the following tables:

Types of products (%)	2002	2005		
Products/substances or devices for human medicine and dentistry and for veterinary medicine	269	689		
Potential or actual contaminants in the general environment which do not appear in other columns	162	0		
Other toxicological or safety evaluations	870	250		

In 2005, the number of animals used to test Products/substances or devices for human medicine and dentistry and for veterinary medicine were the following:

300 animals in Carcinogenicity and Mutagenicity (in 2002, they were 100 animals);

261 animals in Irritation/sensitisation tests (in 2002, they were 85 animals);

103 animals in Acute and sub-acute toxicity testing methods (including limit test) (in 2002, they were 40 animals).

25 animals in Other tests (in 2002, they were 44 animals).

In 2005, the number of animals used in the category Other toxicological or safety evaluations were 250 animals in Acute and sub-acute toxicity testing methods (including limit test) (in 2002, they were 230 animals in Acute and sub-acute toxicity testing methods (including limit test) and 640 animals in Reproductive and developmental toxicity tests).

TABLE 1: NUMBER OF ANIMALS USED IN RELATION TO THEIR PLACE OF ORIGIN

Origin versus species

1.1 Species	1.2 Total	1.3 Animals coming from registered breeding or supplying establishments within the reporting	1.4 Animals coming from elsewhere in the EC	1.5 Animals coming from Member Countries of the Council of Europe which are	1.6 Animals coming from other origins	1.7 Re-used animals
		country		parties to the Convention ETS 123 (excluding EC Member States)		
1.a. Mice (Mus musculus)	28318	19975	5838	49	2456	50
1.b. Rats (Rattus norvegicus)	6793	2362	4236		195	
1.c. Guinea-Pigs (Cavia porcellus)	379	102			277	
1.d. Hamsters (Mesocricetus)	129	18	111			
1.e. Other Rodents (other <i>Rodentia</i>)						
1.f. Rabbits (Oryctolagus cuniculus)	594	349			245	20
1.g. Cats (Felis catus)						
1.h. Dogs (Canis familiaris)	36				36	10
1.i. Ferrets (Mustela putorius furo)						
1.j. Other Carnivores (other <i>Carnivora</i>)						
1.k. Horses, donkeys and cross breds (<i>Equidae</i>)	8					
1.1. Pigs (Sus)	113					
1.m. Goats (Capra)	4					
1.n. Sheep (Ovis)	290					
1.o. Cattle (Bos)	45					
1.p. Prosimians (<i>Prosimia</i>)						
1.q. New World Monkeys (Ceboidea)						
1.r. Old World Monkeys (Cercopithecoidea)						
1.s. Apes (Hominoidea)						
1.t. Other Mammals (other Mammalia)	1					
1.u. Quail (Coturnix coturnix)						
1.v. Other birds (other <i>Aves</i>)	112					
1.w. Reptiles (Reptilia)						12
1.x. Amphibians (Amphibia)	51				1	
1.y. Fish (Pisces)	4748					
1.z. TOTAL	41621					

Note 1: Column 1.5 concerns only those Member Countries of the Council of Europe which, at the beginning of the reporting period, are Parties to the Convention ETS 123. Thus an updated list of those countries has to be used when filling in this column.

Note 2: Only the white boxes need to be completed.

Note 3: The number of re-used animals in column 1.7 should be excluded from the total in the column 1.2

TABLE 2: NUMBER OF ANIMALS USED IN EXPERIMENTS FOR SELECTED PURPOSES

Purpose versus species

	2.1	2.2	2.3	2.4	2.5	2.6	2.7	2.8	2.9	2.10
	Species	Biological	Research and	Production and	Production and	Toxicological	Diagnosis of	Education and	Other	Total
		studies of a	development of	quality control of	quality control of	and other safety	disease	training		
		fundamenta	products and	products and	products and	evaluations				
		l nature	devices for human	devices for	devices for	(including				
			medicine and	human medicine	veterinary	safety				
			dentistry and for	and dentistry	medicine	evaluation of				
			veterinary			products and				
			medicine			devices for				
			(excluding toxicological and			human medicine and				
			other safety			dentistry and				
			evaluations			for veterinary				
			counted in column			medicine)				
			2.6)			meareme)				
2.a.	Mice	23396	1075	700	977	440	994	471	265	28318
2.b.	Rats	4249	1612			200	113	561	58	6793
2.c.	Guinea-Pigs	65			110	2	8	25	169	379
2.d.	Hamsters		115						14	129
2.e.	Other Rodents									
2.f.	Rabbits	3	19	15	245	261	1	25	25	594
2.g.	Cats									
2.h.	Dogs					36				36
2.i.	Ferrets									
2.j.	Other Carnivores									
2.k.	Horses, donkeys and cross							8		8
	breds									
2.1.	Pigs	33						78	2	113
2.m.	Goats							4		4
2.n.	Sheep	272			4			8	6	290
2.0.	Cattle	37						8		45
2.p.	Prosimians									
2.q.	New World Monkeys									
2.r.	Old World Monkeys									
2.s.	Apes									
2.t.	Other Mammals		1							1
2.u.	Quail									
2.v.	Other birds	6			69				37	112
2.w.	Reptiles									
2.x.	Amphibians							50	1	51
2.y.	Fish	4728						20		4748
2.z.	TOTAL	32789	2822	715	1405	939	1116	1258	577	41621

TABLE 3: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS

Products versus species

	3.1	3.2	3.3	3.4	3.5	3.6	3.7	3.8	3.9	3.10	3.11
	Species	Products/	Products/	Products/	Products/	Products/	Products/	Products/	Potential or	Other toxico-	Total
	-	substances or	substances	substances	substances	substances	substances	substances	actual contami-	logical or	
		devices for	used or	used or	used or	used or	used or	used or	nants in the	safety	
		human	intended to	intended to	intended to	intended to	intended to be	intended to be	general envi-	evaluations	
		medicine and	be used	be used	be used	be used	used mainly	used mainly	ronment which		
		dentistry and	mainly in	mainly in	mainly in	mainly as	as additives in	as additives in	do not appear in		
		for veterinary	agriculture	industry	the	cosmetics	food for	food for	other columns		
		medicine			household	or toiletries	human	animal			
							consumption	consumption			
3.a.	Mice	190								250	440
3.b.	Rats								200		
3.c.	Guinea-Pigs	2									2
3.d.	Hamsters										
3.e.	Other Rodents										
3.f.	Rabbits	261									261
3.g.	Cats										
3.h.	Dogs	36									36
3.i.	Ferrets										
3.j.	Other Carnivores										
3.k.	Horses, donkeys and cross breds										
3.1.	Pigs										
3.m.	Goats										
3.n.	Sheep										
3.o.	Cattle										
3.p.	Prosimians										
3.q.	New World Monkeys										
3.r.	Old World Monkeys										
3.s.	Apes										
3.t.	Other Mammals										
3.u.	Quail										
3.v.	Other birds										
3.w.	Reptiles										
3.x.	Amphibians										
3.y.	Fish										
3.z.	TOTAL	489							200	250	939

TABLE 4: NUMBER OF ANIMALS USED IN EXPERIMENTS FOR STUDIES ON HUMAN AND ANIMAL DISEASES

Main categories versus species

	4.1	4.2	4.3	4.4	4.5	4.6	4.7
	Species	Human cardiovascular	Human nervous and	Human cancer (excluding	Other human diseases	Studies specific to animal	Total
		diseases	mental disorders	evaluations of carcinogenic		diseases	
				hazards or risks)			
4.a.	Mice	66	2126	436	12509	247	15384
4.b.	Rats	459	2696	3	658		3816
4.c.	Guinea-Pigs				2		2
4.d.	Hamsters	111			14		125
4.e.	Other Rodents						
4.f.	Rabbits						
4.g.	Cats						
4.h.	Dogs						
4.i.	Ferrets						
4.j.	Other Carnivores						
4.k.	Horses, donkeys and cross breds						
4.1.	Pigs			2		2	4
4.m.	Goats						
4.n.	Sheep					4	4
4.0.	Cattle						
4.p.	Prosimians						
4.q.	New World Monkeys						
4.r.	Old World Monkeys						
4.s.	Apes						
4.t.	Other Mammals						
4.u.	Quail						
4.v.	Other birds		-		19	18	37
4.w.	Reptiles						
4.x.	Amphibians						
4.y.	Fish						
4.z.	TOTAL	636	4822	441	13202	271	19372

TABLE 5: NUMBER OF ANIMALS USED IN PRODUCTION AND QUALITY CONTROL OF PRODUCTS AND DEVICES FOR HUMAN MEDICINE AND DENTISTRY AND FOR VETERINARY MEDICINE

Regulatory requirements versus species

5.b. F 5.c. C 5.d. H 5.e. C 5.f. F	5.1 Species Mice Rats Guinea-Pigs Hamsters Other Rodents Rabbits Cats Dogs	5.2 National legislation specific to a single EC Member State 1) 977 110	5.3 EC legislation including European Pharmacopoeia (requirements)	5.4 Member Country of Council of Europe (but not EC) legislation 2)	5.5 Other legislation	5.6 Any combination of 5.2/ 5.3/ 5.4/ 5.5	5.7 No regulatory requirements	5.8 Total 1677
5.b. F 5.c. C 5.d. H 5.e. C 5.f. F	Mice Rats Guinea-Pigs Hamsters Other Rodents Rabbits Cats	specific to a single EC Member State 1) 977 110	including European Pharmacopoeia (requirements)	of Europe (but not EC) legislation	Other legislation	Any combination of 5.2/ 5.3/ 5.4/ 5.5	requirements	1677
5.b. F 5.c. C 5.d. H 5.e. C 5.f. F	Mice Rats Guinea-Pigs Hamsters Other Rodents Rabbits Cats	specific to a single EC Member State 1) 977 110	including European Pharmacopoeia (requirements)	of Europe (but not EC) legislation		5.2/ 5.3/ 5.4/ 5.5	requirements	
5.b. F 5.c. C 5.d. H 5.e. C 5.f. F	Rats Guinea-Pigs Hamsters Other Rodents Rabbits Cats	Member State 1) 977 110	Pharmacopoeia (requirements)	legislation				
5.b. F 5.c. C 5.d. H 5.e. C 5.f. F	Rats Guinea-Pigs Hamsters Other Rodents Rabbits Cats	1) 977 110	(requirements)				700	
5.b. F 5.c. C 5.d. H 5.e. C 5.f. F	Rats Guinea-Pigs Hamsters Other Rodents Rabbits Cats	977					700	
5.b. F 5.c. C 5.d. H 5.e. C 5.f. F	Rats Guinea-Pigs Hamsters Other Rodents Rabbits Cats	110	40					
5.c. C 5.d. H 5.e. C 5.f. F	Hamsters Other Rodents Rabbits Cats		40					110
5.d. H 5.e. C 5.f. R	Hamsters Other Rodents Rabbits Cats	220	40					
5.e. C 5.f. F	Other Rodents Rabbits Cats	220	40					
	Cats	220	40					
			40					260
5.g. (Dogs							
5.h. I								
5.i. F	Ferrets							
	Other Carnivores							
5.k. F	Horses, donkeys and cross breds							
	Pigs							
	Goats							
5.n. S	Sheep	4						4
	Cattle							
	Prosimians							
	New World Monkeys							
	Old World Monkeys							
	Apes							
	Other Mammals							
	Quail							
	Other birds	69						69
	Reptiles							
	Amphibians							
	Fish							
5.z. T	TOTAL TOTAL	1380	40	N-4		41	700	2120

Examples:

5.2 – France is testing due to a UK (or FR) specific requirement

5.3 - UK is testing according to EC legislation

5.4 – Spain is testing due to a Hungarian requirement

5.5 – Sweden is testing due to a US specific requirement

5.6 - Germany is testing due to a Czech requirement (also an EC

requirement)

Note:

Example:

columns 5.2 - 5.5 refer to the legislation imposing that the test be carried out and not to the body which has issued the actual test method, guideline or protocol.

a test required by French legislation and carried out in Belgium according to an

ISO protocol must be coded as a national (FR) legislative requirement and be

entered into column 5.2 in the tables submitted by Belgium.

Footnotes:

1) EC Member States: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden, United Kingdom

Member Countries of Council of Europe (non-EC): Albania, Andorra, Bulgaria, Croatia, Cyprus, Czech Rep., Estonia, Hungary, Iceland, Latvia, Liechtenstein, Lithuania, Malta, Moldova, Norway, Poland, Romania, Russia, San Marino, Slovakia, Slovenia, Switzerland, 'the former Yugoslav Rep. of Macedonia', Turkey, Ukraine

TABLE 6: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS

Regulatory requirements versus species

	6.1 Species	6.2 National legislation specific to a single EC Member State 1)	6.3 EC legislation including European Pharmacopoeia (requirements)	6.4 Member Country of Council of Europe (but not EC) legislation 2)	6.5 Other legislation	6.6 Any combination of 6.2/ 6.3/ 6.4/ 6.5	6.7 No regulatory requirements	6.8 Total
6.a.	Mice	25	315	,			100	440
6.b.	Rats	200						200
6.c.	Guinea-Pigs		2					2
6.d.	Hamsters							
6.e.	Other Rodents							
6.f.	Rabbits		261					261
6.g.	Cats							
6.h.	Dogs		36					36
6.i.	Ferrets							
6.j.	Other Carnivores							
6.k.	Horses, donkeys and cross breds							
6.l.	Pigs							
6.m.	Goats							
6.n.	Sheep							
6.o.	Cattle							
6.p.	Prosimians							
6.q.	New World Monkeys							
6.r.	Old World Monkeys							
6.s.	Apes							
6.t.	Other Mammals							
6.u.	Quail							
6.v.	Other birds							
6.w.	Reptiles							
6.x.	Amphibians							
6.y.	Fish							
6.z.	TOTAL	225	614				100	939

Examples:

6.2 – France is testing due to a UK (or FR) specific requirement

6.3 - UK is testing according to EC legislation

6.4 – Spain is testing due to a Hungarian requirement

6.5 – Sweden is testing due to a US specific requirement

6.6 - Germany is testing due to a Czech requirement (also an EC

requirement)

Example:

Note:

not to the body which has issued the actual test method, guideline or protocol. a test required by French legislation and carried out in Belgium according to an

columns 6.2 - 6.5 refer to the legislation imposing that the test be carried out and

ISO protocol must be coded as a national (FR) legislative requirement and be

entered into column 6.2 in the tables submitted by Belgium.

Footnotes:

1) EC Member States: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden, United Kingdom

Member Countries of Council of Europe (non-EC): Albania, Andorra, Bulgaria, Croatia, Cyprus, Czech Rep., Estonia, Hungary, Iceland, Latvia, Liechtenstein, Lithuania, Malta, Moldova, Norway, Poland, Romania, Russia, San Marino, Slovakia, Slovenia, Switzerland, 'the former Yugoslav Rep. of Macedonia', Turkey, Ukraine

TABLE 7: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS

Types of tests versus species

	7.1		7.2		7.3	7.4	7.5	7.6	7.7	7.8	7.9	7.10	7.11	7.12	7.13
	Species	Acute and su	ab-acute toxicity to the control of	testing methods	Skin irritation	Skin sensitisatio	Eye irritation	Sub- chronic and	Carcino- genicity	Develop- mental	Muta- genicit	Repro- ductive	Toxicity to aquatic	Other	Total
		'	(merading mint to	251)	iiiitatioii	n	iiiitatioii	chronic	gemeny	toxicity	y	toxicity	vertebra-		
								toxicity		tomerty	,	tomeny	tes not		
													included		
													in other		
													columns		
		7.2.1.	7.2.2	7.2.3											
		LD50,	Other lethal	Non lethal											
		LC50	methods	clinical signs											
7 -	Mice	100	215	methods							100			25	440
7.a. 7.b.	Rats	100	215						200		100			25	440 200
7.c.	Guinea-Pigs		2						200						200
7.d.	Hamsters														
7.d. 7.e.	Other Rodents														
7.f.	Rabbits						261								261
7.s.	Cats						201								201
7.h.	Dogs			36											36
7.i.	Ferrets			30											- 30
7.j.	Other Carnivores														
7.k.	Horses, donkeys and cross														
,	breds														
7.1.	Pigs														
7.m.	Goats														
7.n.	Sheep														
7.o.	Cattle														
7.p.	Prosimians														
7.q.	New World Monkeys														
7.r.	Old World Monkeys														
7.s.	Apes														
7.t.	Other Mammals														
7.u.	Quail														
7.v.	Other birds														
7.w.	Reptiles	-				·									
7.x.	Amphibians														
7.y.	Fish														
7.z.	TOTAL	100	217	36			261		200		100			25	939

TABLE 8: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS

Types of tests versus products

	8.1 Products		8.2 nd sub-acute tox ods (including li		8.3 Skin irritation	8.4 Skin sensitisatio	8.5 Eye irritation	8.6 Sub- chronic	8.7 Carcino genicity	8.8 Develop- mental	8.9 Muta- genicit	8.10 Reproductive	8.11 Toxicity to aquatic	8.12 Other	8.13 Total
						n		and chronic toxicity		toxicity	у	toxicity	vertebra- tes not included in other columns		
		8.2.1. LD50, LC50	8.2.2 Other lethal methods	8.2.3 Non lethal clinical signs methods											
8.a.	Products/substances or devices for human medicine and dentistry and for veterinary medicine		103				261		200		100			25	689
8.b.	Products/substances used or intended to be used mainly in agriculture														
8.c.	Products/substances used or intended to be used mainly in industry														
8.d.	Products/substances used or intended to be used mainly in the household														
8.e.	Products/substances used or intended to be used mainly as cosmetics or toiletries														
8.f.	Products/substances used or intended to be used mainly as additives in food for human consumption														
8.g.	Products/substances used or intended to be used mainly as additives in food for animal consumption														
8.h.	Potential or actual contaminants in the general environment which do not appear in other columns														
8.i.	Other toxicological or safety evaluations	100	150												250
8.j.	TOTAL	100	253				261		200		100			25	939

FINLAND

Statistical data submitted

The statistical data have been submitted by the "Maa - ja metsätalousministeriö Elintarvike-ja terveysosasto" (Ministry of Agriculture and Forestry, Veterinary and Food Department).

Comments of Finnish authorities

Report from Finland 2005

In year 2005, 256826 experimental animals were used in Finland. Fish were used 20 % more than in 2004. The total amount of animals of other species used in experiments remained essentially unchanged from the previous year.

Due to the increase in fish use there was a 6 % increase in the total number of experimental animals in 2005 in comparison to 2004. In recent years fish use has varied greatly from more than 500 000 in years 2001 and 2002 to 78 000 in year 2004 causing a great yearly variation in total number of experimental animals used in Finland.

The number of mice used in 2005 was 19 % higher than the yearly average in 2000-2004, but of rats 12% lower, respectively. Of all experimental animals used 60 % were rodents, and 93 % of fish are excluded from the total, respectively. No cats were used in Finland in 2005, but the number of dogs used was increasing third year in row, the number being 103 in 2005 which is 60 % higher than the average yearly use of previous 5 years. Cattle was in 2005 used also increasingly in comparison to previous 5 years. In other species no tendency was seen.

No cats, monkeys and reptiles were reported used as experimental animals in Finland in 2005.

Major part (87 %) of the animals were used for biological studies of a fundamental nature. Animal use in 2005 for human and veterinary medicine research and quality control was 9,3 %, for toxicological and other safety evaluations 0,9 %, for diagnosis of disease 0,2 %, for education and training 1,8 % and other uses 0,9 % of the total number of experimental animals used, respectively. No major differences in comparison to the previous year were observed.

Preparations for a revision of the Finnish legislation concerning use of experimental animals proceeded to final drafts during year 2005 and was planned to be passed in 2006.

Ministry of Agriculture and Forestry funded Finnish research for studies to replace existing techniques using experimental animals with alternative methods with 27 000 € in year 2005.

TABLE 1: NUMBER OF ANIMALS USED IN RELATION TO THEIR PLACE OF ORIGIN

Origin versus species

1.1	1.2	1.3	1.4	1.5	1.6	1.7
Species	Total	Animals coming from registered	Animals coming from	Animals coming from	Animals coming from	Re-used animals
Species	1000	breeding or supplying	elsewhere in the EC	Member Countries of the	other origins	Tto used ummais
		establishments within the reporting	olde where in the 20	Council of Europe which are	ouner origins	
		country		parties to the Convention ETS		
		j		123 (excluding EC Member		
				States)		
1.a. Mice (Mus musculus)	120636	87684	32362	247	343	
1.b. Rats (Rattus norvegicus)	28358	10869	17365		124	
1.c. Guinea-Pigs (Cavia porcellus)	563		563			
1.d. Hamsters (Mesocricetus)	126	6	120			
1.e. Other Rodents (other <i>Rodentia</i>)	3187					
1.f. Rabbits (Oryctolagus cuniculus)	1214	500	714			
1.g. Cats (Felis catus)	0	0				
1.h. Dogs (Canis familiaris)	103	8	95			
1.i. Ferrets (Mustela putorius furo)	80	80				
1.j. Other Carnivores (other <i>Carnivora</i>)	5					
1.k. Horses, donkeys and cross breds (Equidae)	125					
1.1. Pigs (<i>Sus</i>)	1471					
1.m. Goats (Capra)	73					
1.n. Sheep (Ovis)	445					
1.o. Cattle (<i>Bos</i>)	455					
1.p. Prosimians (<i>Prosimia</i>)	0	0				
1.q. New World Monkeys (Ceboidea)	0	0				
1.r. Old World Monkeys (Cercopithecoidea)	0	0				
1.s. Apes (Hominoidea)	0	0				
1.t. Other Mammals (other <i>Mammalia</i>)	972	0				
1.u. Quail (Coturnix coturnix)	0	0				
1.v. Other birds (other <i>Aves</i>)	5773					
1.w. Reptiles (Reptilia)	0					
1.x. Amphibians (Amphibia)	20					
1.y. Fish (Pisces)	93220					
1.z. TOTAL	256826	100617	51229	247	468	0

Note 1: Column 1.5 concerns only those Member Countries of the Council of Europe which, at the beginning of the reporting period, are Parties to the Convention ETS 123. Thus an updated list of those countries has to be used when filling in this column.

Note 2: Only the white boxes need to be completed.

Note 3: The number of re-used animals in column 1.7 should be excluded from the total in the column 1.2

TABLE 2: NUMBER OF ANIMALS USED IN EXPERIMENTS FOR SELECTED PURPOSES

Purpose versus species

	2.1	2.2	2.3	2.4	2.5	2.6	2.7	2.8	2.9	2.10
	Species	Biological	Research and	Production and	Production and	Toxicological	Diagnosis of	Education and	Other	Total
	•	studies of a	development of	quality control of	quality control of	and other safety	disease	training		
		fundamenta	products and	products and	products and	evaluations				
		1 nature	devices for human	devices for	devices for	(including				
			medicine and	human medicine	veterinary	safety				
			dentistry and for	and dentistry	medicine	evaluation of				
			veterinary			products and				
			medicine			devices for				
			(excluding toxicological and			human medicine and				
			other safety			dentistry and				
			evaluations			for veterinary				
			counted in column			medicine)				
			2.6)			medieme)				
2.a.	Mice	111502	7761	100		585	25	581	82	120636
2.b.	Rats	13749	11885	100		1374	17	791	442	28358
2.c.	Guinea-Pigs		352	24		79		24	84	563
2.d.	Hamsters	126								126
2.e.	Other Rodents	3187								3187
2.f.	Rabbits	514	467	54		75	1	85	18	1214
2.g.	Cats									0
2.h.	Dogs		47			56				103
2.i.	Ferrets	80								80
2.j.	Other Carnivores	5								5
2.k.	Horses, donkeys and cross breds	110	15							125
2.1.	Pigs	445	141	203				82	600	1471
2.m.	Goats		4					69		73
2.n.	Sheep	22	43	380						445
2.o.	Cattle	277						178		455
2.p.	Prosimians									0
2.q.	New World Monkeys									0
2.r.	Old World Monkeys									0
2.s.	Apes									0
2.t.	Other Mammals	972								972
2.u.	Quail									0
2.v.	Other birds	2515	8		2209			41	1000	5773
2.w.	Reptiles									0
2.x.	Amphibians							20		20
2.y.	Fish	90011				72	317	2820		93220
2.z.	TOTAL	223515	20723	861	2209	2241	360	4691	2226	256826

TABLE 3: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS

Products versus species

	3.1	3.2	3.3	3.4	3.5	3.6	3.7	3.8	3.9	3.10	3.11
	Species	Products/	Products/	Products/	Products/	Products/	Products/	Products/	Potential or	Other toxico-	Total
		substances or	substances	substances	substances	substances	substances	substances	actual contami-	logical or	
		devices for	used or	used or	used or	used or	used or	used or	nants in the	safety	
		human	intended to	intended to	intended to	intended to	intended to be	intended to be	general envi-	evaluations	
		medicine and	be used	be used	be used	be used	used mainly	used mainly	ronment which		
		dentistry and	mainly in	mainly in	mainly in	mainly as	as additives in	as additives in	do not appear in		
		for veterinary	agriculture	industry	the	cosmetics	food for	food for	other columns		
		medicine			household	or toiletries	human	animal			
							consumption	consumption			
3.a.	Mice	265								320	585
3.b.	Rats	758								616	1374
3.c.	Guinea-Pigs	79									79
3.d.	Hamsters										0
3.e.	Other Rodents										0
3.f.	Rabbits	75									75
3.g.	Cats										0
3.h.	Dogs	56									56
3.i.	Ferrets										0
3.j.	Other Carnivores										0
3.k.	Horses, donkeys and cross breds										0
3.1.	Pigs										0
3.m.	Goats										0
3.n.	Sheep										0
3.o.	Cattle										0
3.p.	Prosimians										0
3.q.	New World Monkeys										0
3.r.	Old World Monkeys										0
3.s.	Apes										0
3.t.	Other Mammals										0
3.u.	Ouail										0
3.v.	Other birds										0
3.w.	Reptiles										0
3.x.	Amphibians										0
3.y.	Fish								72		72
3.z.	TOTAL	1233	0	0	0	0	0	0	72	936	2241

TABLE 4: NUMBER OF ANIMALS USED IN EXPERIMENTS FOR STUDIES ON HUMAN AND ANIMAL DISEASES

Main categories versus species

	4.1	4.2	4.3	4.4	4.5	4.6	4.7
	Species	Human cardiovascular	Human nervous and	Human cancer (excluding	Other human diseases	Studies specific to animal	Total
		diseases	mental disorders	evaluations of carcinogenic		diseases	
				hazards or risks)			
4.a.	Mice	3629	6400	8652	18885		37566
4.b.	Rats	3408	9683	266	4118		17475
4.c.	Guinea-Pigs	332					332
4.d.	Hamsters				120		120
4.e.	Other Rodents						0
4.f.	Rabbits	195	15		362		572
4.g.	Cats						0
4.h.	Dogs	75	12				87
4.i.	Ferrets						0
4.j.	Other Carnivores						0
4.k.	Horses, donkeys and cross breds						0
4.1.	Pigs	218					218
4.m.	Goats						0
4.n.	Sheep				39	22	61
4.0.	Cattle					6	6
4.p.	Prosimians						0
4.q.	New World Monkeys						0
4.r.	Old World Monkeys						0
4.s.	Apes						0
4.t.	Other Mammals					6	6
4.u.	Quail						0
4.v.	Other birds		-			8	8
4.w.	Reptiles	·			·	_	0
4.x.	Amphibians						0
4.y.	Fish					385	385
4.z.	TOTAL	7857	16110	8918	23524	427	56836

TABLE 5: NUMBER OF ANIMALS USED IN PRODUCTION AND QUALITY CONTROL OF PRODUCTS AND DEVICES FOR HUMAN MEDICINE AND DENTISTRY AND FOR VETERINARY MEDICINE

Regulatory requirements versus species

	5.1	5.2	5.3	5.4	5.5	5.6	5.7	5.8
	Species	National legislation	EC legislation	Member Country of Council	Other legislation	Any combination of	No regulatory	Total
		specific to a single EC	including European	of Europe (but not EC)		5.2/ 5.3/ 5.4/ 5.5	requirements	
		Member State	Pharmacopoeia	legislation				
		1)	(requirements)	2)				
5.a.	Mice		80	20				100
5.b.	Rats						100	100
5.c.	Guinea-Pigs						24	24
5.d.	Hamsters							0
5.e.	Other Rodents							0
5.f.	Rabbits		4				50	54
5.g.	Cats							0
5.h.	Dogs							0
5.i.	Ferrets							0
5.j.	Other Carnivores							0
5.k.	Horses, donkeys and cross breds							0
5.1.	Pigs					171	32	203
5.m.	Goats							0
5.n.	Sheep					380		380
5.o.	Cattle							0
5.p.	Prosimians							0
5.q.	New World Monkeys							0
5.r.	Old World Monkeys							0
5.s.	Apes							0
5.t.	Other Mammals							0
5.u.	Quail							0
5.v.	Other birds		·				2209	2209
5.w.	Reptiles							0
5.x.	Amphibians							0
5.y.	Fish							0
5.z.	TOTAL	0	84	20	0	551	2415	3070

Examples:

5.2 – France is testing due to a UK (or FR) specific requirement

5.3 - UK is testing according to EC legislation

5.4 – Spain is testing due to a Hungarian requirement

5.5 – Sweden is testing due to a US specific requirement

5.6 - Germany is testing due to a Czech requirement (also an EC requirement)

Note: columns 5.2 - 5.5 refer to the legislation imposing that the test be carried out and

not to the body which has issued the actual test method, guideline or protocol.

a test required by French legislation and carried out in Belgium according to an

ISO protocol must be coded as a national (FR) legislative requirement and be

entered into column 5.2 in the tables submitted by Belgium.

Footnotes:

EC Member States: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden, United Kingdom

Member Countries of Council of Europe (non-EC): Albania, Andorra, Bulgaria, Croatia, Cyprus, Czech Rep., Estonia, Hungary, Iceland, Latvia, Liechtenstein, Lithuania, Malta, Moldova, Norway, Poland, Romania, Russia, San Marino, Slovakia, Slovenia, Switzerland, 'the former Yugoslav Rep. of Macedonia', Turkey, Ukraine

Example:

NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS TABLE 6:

Regulatory requirements versus species

	6.1	6.2	6.3	6.4	6.5	6.6	6.7	6.8
	Species	National legislation	EC legislation	Member Country of Council	Other legislation	Any combination of	No regulatory	Total
	_	specific to a single EC	including European	of Europe (but not EC)		6.2/ 6.3/ 6.4/ 6.5	requirements	
		Member State	Pharmacopoeia	legislation			-	
		1)	(requirements)	2)				
6.a.	Mice	40	55			490		585
6.b.	Rats		127			1151	96	1374
6.c.	Guinea-Pigs					79		79
6.d.	Hamsters							0
6.e.	Other Rodents							0
6.f.	Rabbits		8			67		75
6.g.	Cats							0
6.h.	Dogs		56					56
6.i.	Ferrets							0
6.j.	Other Carnivores							0
6.k.	Horses, donkeys and cross breds							0
6.l.	Pigs							0
6.m.	Goats							0
6.n.	Sheep							0
6.0.	Cattle							0
6.p.	Prosimians							0
6.q.	New World Monkeys							0
6.r.	Old World Monkeys							0
6.s.	Apes							0
6.t.	Other Mammals							0
6.u.	Quail							0
6.v.	Other birds							0
6.w.	Reptiles							0
6.x.	Amphibians							0
6.y.	Fish						72	72
6.z.	TOTAL	40	246	0	0	1787	168	2241

Examples:

6.2 – France is testing due to a UK (or FR) specific requirement

Note:

columns 6.2 - 6.5 refer to the legislation imposing that the test be carried out and

6.3 - UK is testing according to EC legislation 6.4 – Spain is testing due to a Hungarian requirement

not to the body which has issued the actual test method, guideline or protocol. a test required by French legislation and carried out in Belgium according to an

6.5 – Sweden is testing due to a US specific requirement

Example:

ISO protocol must be coded as a national (FR) legislative requirement and be

6.6 - Germany is testing due to a Czech requirement (also an EC requirement)

entered into column 6.2 in the tables submitted by Belgium.

Footnotes:

EC Member States: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden, United Kingdom

Member Countries of Council of Europe (non-EC): Albania, Andorra, Bulgaria, Croatia, Cyprus, Czech Rep., Estonia, Hungary, Iceland, Latvia, Liechtenstein, Lithuania, Malta, Moldova, Norway, Poland, Romania, Russia, San Marino, Slovakia, Slovenia, Switzerland, 'the former Yugoslav Rep. of Macedonia', Turkey, Ukraine

TABLE 7: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS

Types of tests versus species

	7.1		7.2		7.3	7.4	7.5	7.6	7.7	7.8	7.9	7.10	7.11	7.12	7.13
	Species	Acute and s	ub-acute toxicity	testing methods	Skin	Skin	Eye	Sub-	Carcino-	Develop-	Muta-	Repro-	Toxicity	Other	Total
			(including limit to	est)	irritation	sensitisatio	irritation	chronic and	genicity	mental	genicit	ductive	to aquatic		
						n		chronic toxicity		toxicity	У	toxicity	vertebra- tes not		
								toxicity					included		
													in other		
													columns		
		7.2.1.	7.2.2	7.2.3											
		LD50,	Other lethal	Non lethal											
		LC50	methods	clinical signs											
				methods											
7.a.	Mice			375				40						170	585
7.b.	Rats			520				17				100		737	1374
7.c.	Guinea-Pigs													79	79
7.d.	Hamsters														0
7.e.	Other Rodents													07	0
7.f.	Rabbits							8						67	75
7.g.	Cats							50							0
7.h.	Dogs							56							56
7.i.	Ferrets Other Carnivores														0
7.j.															0
7.k.	Horses, donkeys and cross breds														U
7.1.	Pigs														0
7.n.	Goats														0
7.m.	Sheep														0
7.n.	Cattle														0
7.p.	Prosimians														0
7.q.	New World Monkeys														0
7.r.	Old World Monkeys														0
7.s.	Apes														0
7.t.	Other Mammals														0
7.u.	Quail														0
7.v.	Other birds														0
7.w.	Reptiles														0
7.x.	Amphibians														0
7.y.	Fish												72		72
7.z.	TOTAL	0	0	895	0	0	0	121	0	0	0	100	72	1053	2241

TABLE 8: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS

Types of tests versus products

	8.1 Products		8.2 Acute and sub-acute toxicity testing methods (including limit test)		8.3 Skin irritation	8.4 Skin sensitisatio n	8.5 Eye irritation	8.6 Sub- chronic and chronic toxicity	8.7 Carcino genicity	8.8 Develop- mental toxicity	8.9 Muta- genicit y	8.10 Reproductive toxicity	8.11 Toxicity to aquatic vertebra- tes not included in other columns	8.12 Other	8.13 Total
		8.2.1. LD50, LC50	8.2.2 Other lethal methods	8.2.3 Non lethal clinical signs methods									corumis		
8.a.	Products/substances or devices for human medicine and dentistry and for veterinary medicine			895				121				100		957	2073
8.b.	Products/substances used or intended to be used mainly in agriculture														0
8.c.	Products/substances used or intended to be used mainly in industry														0
8.d.	Products/substances used or intended to be used mainly in the household														0
8.e.	Products/substances used or intended to be used mainly as cosmetics or toiletries														0
8.f.	Products/substances used or intended to be used mainly as additives in food for human consumption														0
8.g.	Products/substances used or intended to be used mainly as additives in food for animal consumption														0
8.h.	Potential or actual contaminants in the general environment which do not appear in other columns												72		72
8.i.	Other toxicological or safety evaluations													96	96
8.j.	TOTAL	0	0	895	0	0	0	121	0	0	0	100	72	1053	2241

SLOVENIA

Statistical data submitted

The statistical data have been submitted by the "Veterinary Administration of the Republic of Slovenia"

Comments of Slovenian authorities

The Slovenian national legislation on the protection of experimental animals has been harmonised with the relevant EU legislation. Experimental animals have been regulated under the Protection of Animals Act (UPB-1, UL RS⁷ 20/04), under the Rules on conditions for experiments on animals (UL RS 88/06), and under the Rules on the Ethical Commission for experiments on animals (UL RS 84/00).

On the basis of annual reports submitted by organisations conducting experiments on animals, the Veterinary Administration of the Republic of Slovenia (VARS) has been keeping statistical records including the data on quantities and species of animals used in experiments and types of experiments as laid down in Article 24 (2) of the Protection of Animals Act. Each user organisation employs an animal welfare expert, who is responsible for compiling on a specifically prescribed form a collective annual report on experiments conducted during the year and for submitting the report by the end of February to VARS. The form envisaged for annual reporting includes eight tables and as Annex 5 constitutes an integral part of the Rules on conditions for experiments on animals.

In the Republic of Slovenia, data on the use of animals in experiments have been collected since 1992. In the period 1992 - 1996, the collective number of animals used in experiments ranged on average up to 33,000 animals, in the period 1997 - 1999 up to 21,000 animals, in the period 2000 - 2001 up to 16,000 animals, and in the period 2002 - 2004 on average up to 13,500 animals. In the light of the above it may be stated with certainty that the use of animals in experiments in the Republic of Slovenia has been showing a downward trend.

In 2005, a collective number of animals used for experimental and other scientific purposes totalled 11,991 animals. As compared to 2004, where 13,538 animals were used in experiments, the number of animals used in experiments in 2005 decreased by 1,547 animals (11.4 %). This collective number of animals mostly included laboratory rodents (mice, rats) and rabbits.

In 2005, 11,344 laboratory rodents were used, amounting to 94.6 % of all experimental animals used, whilst more laboratory rodents were used in 2004, i.e. 12,145 animals or 89.7 % of all experimental animals used. In 2005, 533 rabbits were used in experiments, amounting to 8.5 % less rabbits as compared to 2004. In 2005, a collective number of 114 other animals were used, including in particular sheep, birds, pigs and a horse.

⁷ UL RS – *Uradni list Republike Slovenija* – Official Gazette of the Republic of Slovenia

It is evident from **Table 1** showing the number and species of animals used in relation to their place of origin that nearly all laboratory experimental animals in 2005 came from breeding organisations established within the Republic of Slovenia. Mostly used were laboratory rodents (94.6 %). From the collective number of experimental animals, the animals reused in experiments included the rabbits and dogs.

As regards animals used in experiments for selected purposes as shown in **Table 2**, in 2005, most animals were used in pharmaceutical industry in the Republic of Slovenia. For the purposes of research and development of products and devices for human medicine, and for dentistry and veterinary medicine, for the production and quality control of products and devices for human and veterinary medicine, and for toxicological and other safety evaluations, a total of 9,420 animals, or 78.5 % of all animals used (94 % laboratory rodents, 5.4 % rabbits and 0.4 % sheep), were used in such experiments in 2005.

Table 3 shows that a total of 1,054 animals were used in the toxicological and other safety evaluations. A total of 1,009 animals (975 laboratory rodents and 34 sheep) were used for testing products/substances or devices for human medicine, dentistry and veterinary medicine, and 45 rabbits for other toxicological or safety evaluations.

Table 7 details the use of animals in the toxicological and other safety evaluations. In 2005, 965 laboratory rodents were used in the acute and sub-acute toxicity testing methods, or in LD 50 and LC 50 determination, and 10 laboratory rats, 45 rabbits and 34 sheep in other toxicological and safety evaluations.

Table 8 shows that 965 animals were used in the toxicological and other safety evaluations for products/substances or devices for human medicine, dentistry and veterinary medicine, and 34 animals for other purposes of toxicological or safety evaluations, whilst 55 animals were used in tests of reproduction toxicity of products/substances intended for use in agriculture.

Quality control of products and devices for human medicine, dentistry and veterinary medicine, and toxicological and other safety evaluations of substances are conducted in accordance with the applicable legislation, the requirements of relevant Pharmacopoeias, and in accordance with the international regulations.

Table 5 shows that in accordance with EU legislation, including the requirements of the European Pharmacopoeia, 5,916 animals in total were used in the production and quality control of products and devices for human medicine and dentistry and for veterinary medicine, which amounts to 49.3 % of all experimental animals used in 2005. Laboratory rodents and rabbits were used for these purposes.

The institutes and laboratories of the faculties of human medicine, veterinary medicine, biology and zootechnics use animals in the baseline biological research studies and/or in the research and development studies, and a total of 1,888 animals were used for these purposes in 2005, which amounts to 15.7 % of all animals used, including in particular laboratory rodents (98.9 %), some dogs, sheep and birds.

In 2005, animals were used to a lesser extent for diagnosing diseases (3.1 %), educational and training purposes (2.3 %), and other purposes (0.1 %).

Table 4 shows the number and species of animals used in experiments for studies of diseases in humans and in animals. A total of 1,786 animals were used for these purposes, all for studies of diseases in humans. A total of 735 animals were used for studies of nervous and mental disorders in humans, 422 animals for studies of cardiovascular diseases, and 629 animals for studies of other diseases. Laboratory rodents were used predominantly, and some rabbits and sheep.

An important role in decreasing the number of animals used in experiments plays in particular the legislation, and the substitution of animals by alternative methods where so required by law, the requirement for specific authorisations of experiments, appropriate staff training, successful cooperation between the institutes and researchers at the national and international levels, as well as the active involvement of animal protection and welfare societies. A further important contribution to decreasing the number of animals used in experiments is the responsibility on the part of researchers and their improved attitude towards experimental animals as the plans and protocols of experiments are more precise and detailed, methods more carefully selected and experiments more precisely conducted. Further important factors in decreasing the number of animals used in experiments particularly in the pharmaceutical industry include the interstate/international recognition of results obtained in experiments on animals, the improved biometric methods, improved initial research phases of new substances and the use of cell cultures, tissues or smaller groups of animals.

Dr. Dragica Ornik,

Inspector – Counsellor

Dr. Vida Čadonič Špelič,

Chief Veterinary Officer

TABLE 1: NUMBER OF ANIMALS USED IN RELATION TO THEIR PLACE OF ORIGIN

Origin versus species

1.1	1.2	1.3	1.4	1.5	1.6	1.7
Species	Total	Animals coming from registered	Animals coming from	Animals coming from	Animals coming from	Re-used animals
-F		breeding or supplying	elsewhere in the EC	Member Countries of the	other origins	
		establishments within the reporting		Council of Europe which are		
		country		parties to the Convention ETS		
		-		123 (excluding EC Member		
				States)		
1.a. Mice (Mus musculus)	8556	8556				
1.b. Rats (Rattus norvegicus)	2732	2727	5			
1.c. Guinea-Pigs (Cavia porcellus)	38	38				
1.d. Hamsters (Mesocricetus)	0					
1.e. Other Rodents (other <i>Rodentia</i>)	18					
1.f. Rabbits (Oryctolagus cuniculus)	533	533				466
1.g. Cats (Felis catus)	0					
1.h. Dogs (Canis familiaris)	15	15				6
1.i. Ferrets (Mustela putorius furo)	0					
1.j. Other Carnivores (other <i>Carnivora</i>)	0					
1.k. Horses, donkeys and cross breds (<i>Equidae</i>)	1					
1.1. Pigs (<i>Sus</i>)	16					
1.m. Goats (Capra)	0					
1.n. Sheep (Ovis)	57					
1.o. Cattle (Bos)	0					
1.p. Prosimians (<i>Prosimia</i>)	0					
1.q. New World Monkeys (Ceboidea)	0					
1.r. Old World Monkeys (Cercopithecoidea)	0					
1.s. Apes (Hominoidea)	0					
1.t. Other Mammals (other <i>Mammalia</i>)	0					
1.u. Quail (Coturnix coturnix)	0					
1.v. Other birds (other <i>Aves</i>)	22					
1.w. Reptiles (Reptilia)	3					
1.x. Amphibians (Amphibia)	0					
1.y. Fish (<i>Pisces</i>)	0					
1.z. TOTAL	11991					

Note 1: Column 1.5 concerns only those Member Countries of the Council of Europe which, at the beginning of the reporting period, are Parties to the Convention ETS 123. Thus an updated list of those countries has to be used when filling in this column.

Note 2: Only the white boxes need to be completed.

Note 3: The number of re-used animals in column 1.7 should be excluded from the total in the column 1.2

TABLE 2: NUMBER OF ANIMALS USED IN EXPERIMENTS FOR SELECTED PURPOSES

Purpose versus species

	2.1	2.2	2.3	2.4	2.5	2.6	2.7	2.8	2.9	2.10
	Species	Biological	Research and	Production and	Production and	Toxicological	Diagnosis of	Education and	Other	Total
		studies of a	development of	quality control of	quality control of	and other safety	disease	training		
		fundamenta	products and	products and	products and	evaluations				
		1 nature	devices for human	devices for	devices for	(including				
			medicine and	human medicine	veterinary	safety				
			dentistry and for	and dentistry	medicine	evaluation of				
			veterinary medicine			products and devices for				
			(excluding			human				
			toxicological and			medicine and				
			other safety			dentistry and				
			evaluations			for veterinary				
			counted in column			medicine)				
			2.6)			,				
2.a.	Mice	760	2157	4467	240	478	334	104	16	8556
2.b.	Rats	1087	293	743		497		112		2732
2.c.	Guinea-Pigs	22					9	7		38
2.d.	Hamsters									
2.e.	Other Rodents						16	2		18
2.f.	Rabbits			466		45	1	21		533
2.g.	Cats									
2.h.	Dogs	7						2	6	15
2.i.	Ferrets									
2.j.	Other Carnivores									
2.k.	Horses, donkeys and cross							1		1
	breds									
2.1.	Pigs							16		16
2.m.	Goats									
2.n.	Sheep	5				34	18			57
2.0.	Cattle									
2.p.	Prosimians									
2.q.	New World Monkeys									
2.r.	Old World Monkeys									
2.s.	Apes									
2.t.	Other Mammals									
2.u.	Quail									
2.v.	Other birds	7						15		22
2.w.	Reptiles							3		3
2.x.	Amphibians									
2.y.	Fish									
2.z.	TOTAL	1888	2450	5676	240	1054	378	283	22	11991

TABLE 3: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS

Products versus species

	3.1	3.2	3.3	3.4	3.5	3.6	3.7	3.8	3.9	3.10	3.11
	Species	Products/	Products/	Products/	Products/	Products/	Products/	Products/	Potential or	Other toxico-	Total
		substances or	substances	substances	substances	substances	substances	substances	actual contami-	logical or	
		devices for	used or	used or	used or	used or	used or	used or	nants in the	safety	
		human	intended to	intended to	intended to	intended to	intended to be	intended to be	general envi-	evaluations	
		medicine and	be used	be used	be used	be used	used mainly	used mainly	ronment which		
		dentistry and	mainly in	mainly in	mainly in	mainly as	as additives in	as additives in	do not appear in		
		for veterinary	agriculture	industry	the	cosmetics	food for	food for	other columns		
		medicine			household	or toiletries	human	animal			
							consumption	consumption			
3.a.	Mice	478									478
3.b.	Rats	497									497
3.c.	Guinea-Pigs										
3.d.	Hamsters										
3.e.	Other Rodents										
3.f.	Rabbits									45	45
3.g.	Cats										
3.h.	Dogs										
3.i.	Ferrets										
3.j.	Other Carnivores										
3.k.	Horses, donkeys and cross breds										
3.1.	Pigs										
3.m.	Goats										
3.n.	Sheep	34									34
3.o.	Cattle										
3.p.	Prosimians										
3.q.	New World Monkeys										
3.r.	Old World Monkeys										
3.s.	Apes										
3.t.	Other Mammals										
3.u.	Quail										
3.v.	Other birds										
3.w.	Reptiles										
3.x.	Amphibians										
3.y.	Fish										
3.z.	TOTAL	1009								45	1054

TABLE 4: NUMBER OF ANIMALS USED IN EXPERIMENTS FOR STUDIES ON HUMAN AND ANIMAL DISEASES

Main categories versus species

4.1	4.2	4.3	4.4	4.5	4.6	4.7
Species	Human cardiovascular	Human nervous and	Human cancer (excluding	Other human diseases	Studies specific to animal	Total
	diseases	mental disorders	evaluations of carcinogenic		diseases	
			hazards or risks)			
4.a. Mice	99			426		525
4.b. Rats	323	735		157		1215
4.c. Guinea-Pigs				22		22
4.d. Hamsters						
4.e. Other Rodents				16		16
4.f. Rabbits						
4.g. Cats						
4.h. Dogs						
4.i. Ferrets						
4.j. Other Carnivores						
4.k. Horses, donkeys and cross breds						
4.l. Pigs						
4.m. Goats						
4.n. Sheep				8		8
4.o. Cattle						
4.p. Prosimians						
4.q. New World Monkeys						
4.r. Old World Monkeys						
4.s. Apes						
4.t. Other Mammals						
4.u. Quail						
4.v. Other birds						
4.w. Reptiles						
4.x. Amphibians						
4.y. Fish						
4.z. TOTAL	422	735		629		1786

TABLE 5: NUMBER OF ANIMALS USED IN PRODUCTION AND QUALITY CONTROL OF PRODUCTS AND DEVICES FOR HUMAN MEDICINE AND DENTISTRY AND FOR VETERINARY MEDICINE

Regulatory requirements versus species

	5.1 Species	5.2 National legislation specific to a single EC Member State 1)	5.3 EC legislation including European Pharmacopoeia (requirements)	5.4 Member Country of Council of Europe (but not EC) legislation 2)	5.5 Other legislation	5.6 Any combination of 5.2/5.3/5.4/5.5	5.7 No regulatory requirements	5.8 Total
5.a.	Mice	1)	4707	2)				4707
5.b.	Rats		743					743
5.c.	Guinea-Pigs		773					743
5.d.	Hamsters							
5.e.	Other Rodents							
5.f.	Rabbits		466					466
5.g.	Cats		400					400
5.h.	Dogs							
5.i.	Ferrets							
5.j.	Other Carnivores							
5.k.	Horses, donkeys and cross breds							
5.l.	Pigs							
5.m.	Goats							
5.n.	Sheep							
5.0.	Cattle							
5.p.	Prosimians							
5.q.	New World Monkeys							
5.r.	Old World Monkeys							
5.s.	Apes							
5.t.	Other Mammals							
5.u.	Quail							
5.v.	Other birds							
5.w.	Reptiles							
5.x.	Amphibians							
5.y.	Fish							
5.z.	TOTAL		5916					5916

Examples:

5.2 – France is testing due to a UK (or FR) specific requirement

5.3 - UK is testing according to EC legislation

5.4 – Spain is testing due to a Hungarian requirement

5.5 – Sweden is testing due to a US specific requirement

5.6 - Germany is testing due to a Czech requirement (also an EC requirement)

Note:

Example:

not to the body which has issued the actual test method, guideline or protocol. a test required by French legislation and carried out in Belgium according to an

columns 5.2 - 5.5 refer to the legislation imposing that the test be carried out and

ISO protocol must be coded as a national (FR) legislative requirement and be

entered into column 5.2 in the tables submitted by Belgium.

Footnotes:

EC Member States: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden, United Kingdom

Member Countries of Council of Europe (non-EC): Albania, Andorra, Bulgaria, Croatia, Cyprus, Czech Rep., Estonia, Hungary, Iceland, Latvia, Liechtenstein, Lithuania, Malta, Moldova, Norway, Poland, Romania, Russia, San Marino, Slovakia, Slovenia, Switzerland, 'the former Yugoslav Rep. of Macedonia', Turkey, Ukraine

NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS TABLE 6:

Regulatory requirements versus species

	6.1	6.2	6.3	6.4	6.5	6.6	6.7	6.8
	Species	National legislation	EC legislation	Member Country of Council	Other legislation	Any combination of	No regulatory	Total
		specific to a single EC	including European	of Europe (but not EC)		6.2/ 6.3/ 6.4/ 6.5	requirements	
		Member State	Pharmacopoeia	legislation				
		1)	(requirements)	2)				
6.a. 1	Mice		478					478
	Rats		487			0	10	497
	Guinea-Pigs							0
6.d. 1	Hamsters							0
6.e. (Other Rodents						45	45
6.f. l	Rabbits							0
6.g. (Cats							0
6.h.	Dogs							0
6.i.	Ferrets							0
6.j. (Other Carnivores							0
6.k.	Horses, donkeys and cross breds							0
6.l. l	Pigs							0
6.m. (Goats						34	34
6.n.	Sheep							0
6.0.	Cattle							0
6.p. 1	Prosimians							0
6.q. 1	New World Monkeys							0
6.r. (Old World Monkeys							0
	Apes							0
6.t. (Other Mammals							0
6.u. (Quail							0
6.v. (Other birds							0
6.w. 1	Reptiles							0
6.x.	Amphibians							0
6.y. 1	Fish							0
6.z.	TOTAL	0	965	0	0	0	89	1054

Examples:

6.2 – France is testing due to a UK (or FR) specific requirement

Note:

columns 6.2 - 6.5 refer to the legislation imposing that the test be carried out and

6.3 - UK is testing according to EC legislation

not to the body which has issued the actual test method, guideline or protocol.

6.4 – Spain is testing due to a Hungarian requirement

a test required by French legislation and carried out in Belgium according to an

6.5 – Sweden is testing due to a US specific requirement

Example: ISO protocol must be coded as a national (FR) legislative requirement and be

6.6 - Germany is testing due to a Czech requirement (also an EC requirement)

entered into column 6.2 in the tables submitted by Belgium.

Footnotes:

EC Member States: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden, United Kingdom

Member Countries of Council of Europe (non-EC): Albania, Andorra, Bulgaria, Croatia, Cyprus, Czech Rep., Estonia, Hungary, Iceland, Latvia, Liechtenstein, Lithuania, Malta, Moldova, Norway, Poland, Romania, Russia, San Marino, Slovakia, Slovenia, Switzerland, 'the former Yugoslav Rep. of Macedonia', Turkey, Ukraine

TABLE 7: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS

Types of tests versus species

	7.1		7.2		7.3	7.4	7.5	7.6	7.7	7.8	7.9	7.10	7.11	7.12	7.13
	Species	Acute and si	ub-acute toxicity	testing methods	Skin	Skin	Eye	Sub-	Carcino-	Develop-	Muta-	Repro-	Toxicity	Other	Total
			(including limit to	est)	irritation	sensitisatio	irritation	chronic and	genicity	mental	genicit	ductive	to aquatic		
						n		chronic toxicity		toxicity	у	toxicity	vertebra- tes not		
								toxicity					included		
													in other		
													columns		
		7.2.1.	7.2.2	7.2.3											
		LD50,	Other lethal	Non lethal											
		LC50	methods	clinical signs											
7) ('	470		methods											470
7.a.	Mice Rats	478 487												10	478 497
7.b. 7.c.	Guinea-Pigs	407												10	0
7.d.	Hamsters														0
7.u. 7.e.	Other Rodents														0
7.f.	Rabbits													45	45
7.g.	Cats													70	0
7.h.	Dogs														0
7.i.	Ferrets														0
7.j.	Other Carnivores														0
7.k.	Horses, donkeys and cross														0
	breds														
7.1.	Pigs														0
7.m.	Goats														0
7.n.	Sheep													34	34
7.o.	Cattle														0
7.p.	Prosimians														0
7.q.	New World Monkeys														0
7.r.	Old World Monkeys														0
7.s.	Apes														0
7.t.	Other Mammals														0
7.u. 7.v.	Quail Other birds														0
7.v. 7.w.	Reptiles														0
7.w. 7.x.	Amphibians														0
7.x. 7.y.	Fish														0
7.y. 7.z.	TOTAL	965	0	0	0	0	0	0	0	0	0	0	0	89	1054
/ .L.	1 O 171L	903	U	U	U	U	U	U	U	U	U	U	U	Uð	1004

TABLE 8: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS

Types of tests versus products

	8.1		8.2		8.3	8.4	8.5	8.6	8.7	8.8	8.9	8.10	8.11	8.12	8.13
	Products	meth	nd sub-acute tox ods (including li	imit test)	Skin irritation	Skin sensitisatio n	Eye irritation	Sub- chronic and chronic toxicity	Carcino genicity	Develop- mental toxicity	Muta- genicit y	Repro- ductive toxicity	Toxicity to aquatic vertebra- tes not included in other columns	Other	Total
		8.2.1. LD50, LC50	8.2.2 Other lethal methods	8.2.3 Non lethal clinical signs methods											
8.a.	Products/substances or devices for human medicine and dentistry and for veterinary medicine	965												34	999
8.b.	Products/substances used or intended to be used mainly in agriculture											55			55
8.c.	Products/substances used or intended to be used mainly in industry														0
8.d.	Products/substances used or intended to be used mainly in the household														0
8.e.	Products/substances used or intended to be used mainly as cosmetics or toiletries														0
8.f.	Products/substances used or intended to be used mainly as additives in food for human consumption														0
8.g.	Products/substances used or intended to be used mainly as additives in food for animal consumption														0
8.h.	Potential or actual contaminants in the general environment which do not appear in other columns														0
8.i.	Other toxicological or safety evaluations														0
8.j.	TOTAL	965	0	0	0	0	0	0	0	0	0	55	0	34	1054

SLOVAKIA

Statistical data submitted

The statistical data have been submitted by the State Veterinary and Food Administration of the Slovak Republic, Botanická 17, 842 13 Bratislava

Comments of Slovakian authorities

National comments to the statistical evaluation of data concerning the number of experimental animals used in experiments in the year 2005 in the Slovak Republic.

The State Veterinary and Food Administration of the Slovak Republic (hereinafter "SVFA SR") as a competent authority of the Slovak Republic in the matter of approval of establishments for breeding and use of animals for experimental and other scientific purposes is comprised of 8 Regional Veterinary and Food Administrations (hereinafter RVFA) and 40 District Veterinary and Food Administrations (hereinafter DVFA). All the workers of the veterinary administration in the field of animal welfare are veterinarians.

The SVFA SR approves in compliance with Article 6 of the Act No.488/2002 Coll. on Veterinary Care and on Amendment to Some Laws as later amended (hereinafter Act No. 488/2002 Coll.) and in compliance with Article 7 and Article 13 and 17 of the Ordinance of the Government of Slovak Republic No. 289/2003 Coll., laying down requirements for the protection of animals used for experimental purposes or other scientific purposes as later amended (hereinafter "Ordinance of the Government of the Slovak Republic No. 289/2003 Coll.".), experimental, breeding and supplying establishments and all the experiments performed using animals. Each approved establishment is kept by the SVFA SR on the list of approved establishments on the website of SVFA SR www.svssr.sk. in compliance with Article 37 of the Act No. 488/2002 Coll.

Approval of all kinds of establishments is performed by the SVFA SR based on affirmative standpoint on assessment of the suitability of establishment for housing, breeding, care and the use of animals for experiments, issued by the RVFA) in compliance with Article 12 and 16 of the Ordinance of the Government of the Slovak Republic No.289/2003 Coll. The RVFA issues a standpoint based on results of a control performed directly in the establishment for the purpose of assessment of observance of requirements for approved establishment, which are laid down in the Ordinance of the Government of the Slovak Republic No. 289/2003 Coll. Controls of establishments are performed by veterinarians - RVFA animal welfare inspectors. Animal welfare inspectors shall be obliged, in compliance with Article 7 of the Act 488/2002 Coll. and Article 21 of the Ordinance of the Government of the Slovak Republic No. 289/2003 Coll. to perform minimum once a year non-discriminatory controls of all approved establishments for the purpose of control of observance of requirements for approved establishment which are laid down in the Ordinance of the Government of the Slovak Republic No. 289/2003 Coll. The SVFA SR, as a competent authority, trained theoretically and also practically all the animal welfare

inspectors for the performance of the control. Controls are performed based on methodical instructions and check lists worked out by the competent authority in compliance with requirements laid down in the Ordinance of the Government of the Slovak Republic No. 289/2003 Coll. and in the Act 488/2002 Coll.

The SVFA SR approved in the year 2005, based on applicant's applications a total of 7 new experimental establishments, 1 breeding establishment for breeding of experimental animals.

Total number of establishments in the Slovak Republic in the year 2005

Kind of establishment	Number
Experimental establishment	43
Experimental establishment with breeding of animals for own use	20
Breeding establishment	7
Supplying establishment	1
Total:	71

The SVFA SR approves the experiments performed upon animals based on the application for approval of the experiment submitted by an applicant - approved experimental establishment. Each application for approval of an experiment shall be submitted by an applicant in compliance with Article 20 of the Ordinance of the Government of the Slovak Republic No. 289/2003 Coll. in order to be judged by the ETHIC COMMISSION. Each approved experimental establishment shall have established its own ethic commission comprised of minimum 5 members, out of which 1/3 must not be dependent from the experimental establishment. Ethic commission, on the submitted project of an experiment, shall assess justification of each experiment, use of the animals in the experiment and specification of species and number of animals in the experiment. An applicant may submit his/her project of an experiment for approval by the SVFA SR only after recommendation for submission, issued by the ethic commission. The SVFA SR has in compliance with the Act No. 71/1967 Coll. On Administrative Proceedings (Administrative Codex) minimum 30 days for assessment of an application for approval of the experiment. The SVFA SR. as a competent authority shall issue a decision by which the performance of the experiment may be approved or refused. In approval of the experiment, the SVFA SR shall assess the conformity of purpose of the experiment (3R), methods of performance of the experiment, origin of experimental animals, handling, care and housing of experimental animals with provision laid down in the Ordinance of the Government No. 289/2003 Coll., in compliance with the valid legislation in the Slovak Republic and in the European Union. The SVFA SR established, based on the Article 8 of the Ordinance of the Government of the Slovak Republic No. 289/2003 Coll. advisory body of the chief veterinary officer the members of which are scientific workers in the said branch. The SVFA SR in case of the need of professional consultation concerning the aim of the experiment, the need of use of the animals in the experiment and the number of used animals shall ask the members of the advisory body for opinion - to the submitted application for approval of the experiment- with observance of rules of personal data protection and protection of data with signs of trade secret or intellectual property.

To the Table No. 1 most of experimental animals originate in domestic breeding establishments or in experimental establishments with breeding of animals for own use. As far as foreign suppliers are concerned, the animals originate mainly in the Czech Republic, Hungary, Germany, Poland and France.

To the Table No. 2 The SVFA SR approved 273 experiments with use of experimental animals and suspended the proceeding in 10 applications for approval of the experiment in the year 2005. The total number of used animals does not reflect the number of approved experiments, because in number of used experimental animals also the animals are included which were used in the year 2005 from the experiments, approved in the year 2003, 2004 for the period of 2-3 years. In the column 2.8, in total 7 experiments as pre-experiments for introduction of surgical methods and practices in the course of performance of main experiments were approved.

Number of approved experiments in the Slovak Republic for the year 2005

Dividing of experiments based on the Table No.2 (number of animals used in the experiment for a various purpose) from the statistical notification of the number of used animals

Kind of experiment- purpose of the experiment	Number of experiments performed
2.2. Basic research	70
2.3. Research and development of products and devices for human medicine and veterinary medicine and dentistry	79
2.4. Production and control of quality of products and devices for human medicine and dentistry	5
2.5. Production and control of quality of products and devices for veterinary medicine	10
2.6. Toxicological and other safety evaluations including evaluation of safety of products and devices for human and veterinary medicine and dentistry	62
2.7. Disease diagnostics	25

2.8. Education and training	7
2.9. Other	15
Total	273

To the Table No.3 In the column 3.2 most animals were used for evaluation of products and substances for human medicine. In the column 3.3 the animal was used for control of products/substances used in agriculture- mainly pesticide, herbicide products. In the column 3.4 the animals used for control of various chemical products/ substances being a part of oils, lubricants and rude materials are indicated.

To the Table No. 4 Explanation to the column 4.5. Animals were used for the purpose of investigation of immune systems, infectious diseases, and metabolism disorders in man and in the column 4.6 in animals.

To the Table No. 5 In the Slovak Republic the experiments upon animals are performed in compliance with the valid Slovak legislation, in which the legal acts of the European Communities and the European Union are incorporated. The experiments are performed in compliance with the valid legislation of the European Pharmacopoeia, in the column 5.5 the experiments were performed according to the valid national legislation e.g. STN EN ISO standards. In the column 5.7 the methods in control of human products/substances were used that were created by the experimental establishment as a modified method based on the approved pharmacopoeial methods or as a new individual method.

To the Table No. 6 The Slovak Republic has elaborated the valid legislation for the control of drugs - Act No. 140/1998 Coll. Act On Medicinal Products and Medical Devices as amended, for the control of chemical substances and preparations the Act No. 163/2001 Coll. On Chemical Substances and Preparations, Decree of the Ministry of Economy No. 2/2005 Annex 5 Part B Methods B, that are analogous to OECD methods. In the column 6.3 the number of animals used in compliance with the European Pharmacopoeia are indicated, in the column 6.4 a total of 4 rabbits were used in the experiment of eye irritation in control of a substance used mainly in agriculture.

To the Table No. 7 In the column 7.2.1. the animals were used only in limit test. Tests were performed mainly by methods OECD TG 402, 403. In the column 7.2.2. the tests OECD TG 423, B.1 tris were performed. In the column 7.2.3 mainly tests in compliance with OECD TG 407, 420, tolerance studies were performed.

In compliance with Article 17 para 4 of the Ordinance of the Government of the Slovak Republic No. 289/2003 Coll. each approved establishment shall be obliged, in order to maintain the approval, to submit yearly by the end of January for the previous year to the SVFA SR a notification on the form according to the specimen laid down in the Ordinance of the Government of the Slovak Republic No. 289/2003 Coll. on the number of used animals. Approved establishments shall be obliged to keep records about the number of used GMO animals in the experiment. Based on collected data the SVFA SR shall yearly work out a notification about the activity of the SVFA SR in which the numbers of approved establishments and approved or refused

experiments as well as numbers and species of used animals in the experiment for the respective year are published.

Controls of establishments are performed by veterinarians - RVFA animal welfare inspectors. Animal welfare inspectors shall be obliged, in compliance with Article 7 of the Act 488/2002 Coll. And Article 21 of the Ordinance of the Government of the Slovak Republic No. 289/2003 Coll. to perform minimum once a year non-discriminatory controls of all approved establishments for the purpose of control of observance of requirements for approved establishment indicated in the Ordinance of the Government of the Slovak Republic No. 289/2003 Coll. The SVFA, as a competent authority, has trained theoretically and also practically all the animal welfare inspectors for performance of the control. Controls are performed based on methodical instructions and check lists worked out by the competent authority in compliance with requirements indicated in the Ordinance of the Government of the Slovak Republic No. 289/2003 Coll. and in the Act 488/2002 Coll.

Control of animal welfare in approved establishments is performed by animal welfare inspectors – veterinarians in compliance with Article 8 para 3 letter b) and Article 21 of the Act No. 488/2002 Coll. and of the Ordinance of the Government of the Slovak Republic No. 289/2003 Coll. Controls of animal welfare are non-discriminatory, performed minimum once a year in each approved establishment. The competent authority trained all the inspectors for performance of animal welfare inspection and worked out the methodical instruction according to which the animal welfare inspections are performed. The purpose of animal welfare control in approved establishments is a control of observance of requirements laid down in the Act No. 488/2002 Coll, Ordinance of the Government of the Slovak Republic No. 289/2003 Coll. Animal welfare inspectors shall control conformity of the test performance in an approved experimental establishment with a decision issued by the SVFA SR on the approval of the experiment. Finding of infringements laid down in the Act No. 488/2002 Coll., Article 21 and 44 and in the Ordinance of the Government of the Slovak Republic No. 289/2003 Coll. is classified as an administrative delict for which a penalty may be imposed on a legal or natural person in compliance with Article 45 of the Act No. 488/2002 Coll.

The SVFA SR performs theoretical and practical trainings of all workers of veterinary administration in performance of control with regard to housing, care and protection of experimental animals.

The competent authority performs consulting services for public in the field of animal welfare, organizes trainings for workers of approved establishments the purpose of which is interpretation of the valid legislation of the Slovak Republic in the field of animal welfare. The SVFA SR organizes also seminars and lectures aimed at protection of experimental animals used for experimental purposes. In compliance with the Article 35 of the Act. No. 488/2002 Coll. the animal owner, keeper and dealer shall be obliged to educate demonstrably the persons handling the animals so that such persons must avoid from any acts that might cause injury or any other damage to the health of animals or unnecessary suffering thereof.

Prof. Jozef Bíreš, DVM, DrSc, Chief Veterinary Officer

TABLE 1: NUMBER OF ANIMALS USED IN RELATION TO THEIR PLACE OF ORIGIN

Origin versus species

1.1 Species	1.2 Total	1.3 Animals coming from registered breeding or supplying establishments within the reporting country	1.4 Animals coming from elsewhere in the EC	1.5 Animals coming from Member Countries of the Council of Europe which are parties to the Convention ETS 123 (excluding EC Member States)	1.6 Animals coming from other origins	1.7 Re-used animals
1.a. Mice (Mus musculus)	14975	9246		5729		
1.b. Rats (Rattus norvegicus)	6761	4942	51	1768		
1.c. Guinea-Pigs (Cavia porcellus)	594	514		80		
1.d. Hamsters (Mesocricetus)	0					
1.e. Other Rodents (other <i>Rodentia</i>)						
1.f. Rabbits (Oryctolagus cuniculus)	782	632		150		126
1.g. Cats (Felis catus)	0					
1.h. Dogs (Canis familiaris)	6			6		
1.i. Ferrets (Mustela putorius furo)	0					
1.j. Other Carnivores (other <i>Carnivora</i>)						
1.k. Horses, donkeys and cross breds (<i>Equidae</i>)						
1.1. Pigs (Sus)						
1.m. Goats (Capra)						
1.n. Sheep (Ovis)						
1.o. Cattle (Bos)						
1.p. Prosimians (<i>Prosimia</i>)	0					
1.q. New World Monkeys (Ceboidea)	0					
1.r. Old World Monkeys (Cercopithecoidea)	0					
1.s. Apes (Hominoidea)	0	-	<u> </u>			
1.t. Other Mammals (other <i>Mammalia</i>)						
1.u. Quail (Coturnix coturnix)	251	251				
1.v. Other birds (other <i>Aves</i>)						
1.w. Reptiles (<i>Reptilia</i>)						
1.x. Amphibians (Amphibia)						
1.y. Fish (<i>Pisces</i>)						
1.z. TOTAL	23369					

Note 1: Column 1.5 concerns only those Member Countries of the Council of Europe which, at the beginning of the reporting period, are Parties to the Convention ETS 123. Thus an updated list of those countries has to be used when filling in this column.

Note 2: Only the white boxes need to be completed.

Note 3: The number of re-used animals in column 1.7 should be excluded from the total in the column 1.2

TABLE 2: NUMBER OF ANIMALS USED IN EXPERIMENTS FOR SELECTED PURPOSES

Purpose versus species

	2.1	2.2	2.3	2.4	2.5	2.6	2.7	2.8	2.9	2.10
	Species	Biological	Research and	Production and	Production and	Toxicological	Diagnosis of	Education and	Other	Total
		studies of a	development of	quality control of	quality control of	and other safety	disease	training		
		fundamenta	products and	products and	products and	evaluations				
		l nature	devices for human	devices for	devices for	(including				
			medicine and	human medicine	veterinary	safety				
			dentistry and for	and dentistry	medicine	evaluation of				
			veterinary			products and				
			medicine (excluding			devices for human				
			toxicological and			medicine and				
			other safety			dentistry and				
			evaluations			for veterinary				
			counted in column			medicine)				
			2.6)			,				
2.a.	Mice	7415	2433	117	482	440	3766	100	222	14975
2.b.	Rats	4857	341			1015	292	50	206	6761
2.c.	Guinea-Pigs	252	122	116		84		3	17	594
2.d.	Hamsters									0
2.e.	Other Rodents									0
2.f.	Rabbits	133	39	161	91	159	178	3	18	782
2.g.	Cats									0
2.h.	Dogs					6				6
2.i.	Ferrets									0
2.j.	Other Carnivores									0
2.k.	Horses, donkeys and cross									0
2.1	breds									
2.1.	Pigs									0
2.m.	Goats									0
2.n.	Sheep									0
2.0.	Cattle									0
2.p.	Prosimians									0
2.q.	New World Monkeys									0
2.r.	Old World Monkeys									0
2.s.	Apes									0
2.t.	Other Mammals									0
2.u.	Quail	051								0
2.v.	Other birds	251								251
2.w.	Reptiles									0
2.x.	Amphibians									0
2.y.	Fish	10000	2025	004		4704	4000	450	400	0
2.z.	TOTAL	12908	2935	394	573	1704	4236	156	463	23369

TABLE 3: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS

Products versus species

	3.1	3.2	3.3	3.4	3.5	3.6	3.7	3.8	3.9	3.10	3.11
	Species	Products/	Products/	Products/	Products/	Products/	Products/	Products/	Potential or	Other toxico-	Total
		substances or	substances	substances	substances	substances	substances	substances	actual contami-	logical or	
		devices for	used or	used or	used or	used or	used or	used or	nants in the	safety	
		human	intended to	intended to	intended to	intended to	intended to be	intended to be	general envi-	evaluations	
		medicine and	be used	be used	be used	be used	used mainly	used mainly	ronment which		
		dentistry and	mainly in	mainly in	mainly in	mainly as	as additives in	as additives in	do not appear in		
		for veterinary	agriculture	industry	the	cosmetics	food for	food for	other columns		
		medicine			household	or toiletries	human	animal			
							consumption	consumption			
3.a.	Mice	270	50	120							440
3.b.	Rats	296	121	514			6	75		3	1015
3.c.	Guinea-Pigs	84									84
3.d.	Hamsters										0
3.e.	Other Rodents										0
3.f.	Rabbits	66	10	71				9		3	159
3.g.	Cats										0
3.h.	Dogs	6									6
3.i.	Ferrets										0
3.j.	Other Carnivores										0
3.k.	Horses, donkeys and cross breds										0
3.1.	Pigs										0
3.m.	Goats										0
3.n.	Sheep										0
3.o.	Cattle										0
3.p.	Prosimians										0
3.q.	New World Monkeys										0
3.r.	Old World Monkeys										0
3.s.	Apes										0
3.t.	Other Mammals										0
3.u.	Ouail										0
3.v.	Other birds										0
3.w.	Reptiles										0
3.x.	Amphibians										0
3.y.	Fish										0
3.z.	TOTAL	722	181	705	0	0	6	84	0	6	1704

TABLE 4: NUMBER OF ANIMALS USED IN EXPERIMENTS FOR STUDIES ON HUMAN AND ANIMAL DISEASES

Main categories versus species

	4.1	4.2	4.3	4.4	4.5	4.6	4.7
	Species	Human cardiovascular	Human nervous and	Human cancer (excluding	Other human diseases	Studies specific to animal	Total
		diseases	mental disorders	evaluations of carcinogenic		diseases	
				hazards or risks)			
4.a.	Mice	29	2787	623	8677	1497	13613
4.b.	Rats	1944	1573	181	1792		5490
4.c.	Guinea-Pigs	38			336		374
4.d.	Hamsters						0
4.e.	Other Rodents						0
4.f.	Rabbits		59	8	283		350
4.g.	Cats						0
4.h.	Dogs						0
4.i.	Ferrets						0
4.j.	Other Carnivores						0
4.k.	Horses, donkeys and cross breds						0
4.1.	Pigs						0
4.m.	Goats						0
4.n.	Sheep						0
4.0.	Cattle						0
4.p.	Prosimians						0
4.q.	New World Monkeys						0
4.r.	Old World Monkeys						0
4.s.	Apes						0
4.t.	Other Mammals						0
4.u.	Quail						0
4.v.	Other birds				251		251
4.w.	Reptiles						0
4.x.	Amphibians						0
4.y.	Fish						0
4.z.	TOTAL	2011	4419	812	11339	1497	20078

TABLE 5: NUMBER OF ANIMALS USED IN PRODUCTION AND QUALITY CONTROL OF PRODUCTS AND DEVICES FOR HUMAN MEDICINE AND DENTISTRY AND FOR VETERINARY MEDICINE

Regulatory requirements versus species

	5.1	5.2	5.3	5.4	5.5	5.6	5.7	5.8
	Species	National legislation	EC legislation	Member Country of Council	Other legislation	Any combination of	No regulatory	Total
		specific to a single EC	including European	of Europe (but not EC)		5.2/ 5.3/ 5.4/ 5.5	requirements	
		Member State	Pharmacopoeia	legislation				
		1)	(requirements)	2)				
5.a.	Mice		460		77		62	599
5.b.	Rats							0
5.c.	Guinea-Pigs				116			116
5.d.	Hamsters							0
5.e.	Other Rodents							0
5.f.	Rabbits		107			5	140	252
5.g.	Cats							0
5.h.	Dogs							0
5.i.	Ferrets							0
5.j.	Other Carnivores							0
5.k.	Horses, donkeys and cross breds							0
5.1.	Pigs							0
5.m.	Goats							0
5.n.	Sheep							0
5.o.	Cattle							0
5.p.	Prosimians							0
5.q.	New World Monkeys							0
5.r.	Old World Monkeys							0
5.s.	Apes							0
5.t.	Other Mammals							0
5.u.	Quail							0
5.v.	Other birds							0
5.w.	Reptiles							0
5.x.	Amphibians							0
5.y.	Fish							0
5.z.	TOTAL	0	567	0	193	5	202	967

Examples:

5.2 – France is testing due to a UK (or FR) specific requirement

5.3 - UK is testing according to EC legislation

5.4 – Spain is testing due to a Hungarian requirement

5.5 – Sweden is testing due to a US specific requirement

5.6 - Germany is testing due to a Czech requirement (also an EC

requirement)

Note: Example: columns 5.2 - 5.5 refer to the legislation imposing that the test be carried out and

not to the body which has issued the actual test method, guideline or protocol. a test required by French legislation and carried out in Belgium according to an

ISO protocol must be coded as a national (FR) legislative requirement and be

entered into column 5.2 in the tables submitted by Belgium.

Footnotes:

EC Member States: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden, United Kingdom

Member Countries of Council of Europe (non-EC): Albania, Andorra, Bulgaria, Croatia, Cyprus, Czech Rep., Estonia, Hungary, Iceland, Latvia, Liechtenstein, Lithuania, Malta, Moldova, Norway, Poland, Romania, Russia, San Marino, Slovakia, Slovenia, Switzerland, 'the former Yugoslav Rep. of Macedonia', Turkey, Ukraine

NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS TABLE 6:

Regulatory requirements versus species

	6.1	6.2	6.3	6.4	6.5	6.6	6.7	6.8
	Species	National legislation	EC legislation	Member Country of Council	Other legislation	Any combination of	No regulatory	Total
	•	specific to a single EC	including European	of Europe (but not EC)		6.2/ 6.3/ 6.4/ 6.5	requirements	
		Member State	Pharmacopoeia	legislation			•	
		1)	(requirements)	2)				
6.a. Mice		120	320					440
6.b. Rats		669	346					1015
6.c. Guinea-Pig	gs		84					84
6.d. Hamsters								0
6.e. Other Rode	ents							0
6.f. Rabbits		89	66	4				159
6.g. Cats								0
6.h. Dogs		6						6
6.i. Ferrets								0
6.j. Other Carn								0
6.k. Horses, doi	nkeys and cross breds							0
6.l. Pigs								0
6.m. Goats								0
6.n. Sheep								0
6.o. Cattle								0
6.p. Prosimians	i e							0
6.q. New World								0
6.r. Old World	Monkeys							0
6.s. Apes								0
6.t. Other Mam	nmals							0
6.u. Quail								0
6.v. Other birds	;							0
6.w. Reptiles								0
6.x. Amphibian	is							0
6.y. Fish	·							0
6.z. TOTAL	·	884	816	4	0	0	0	1704

Examples:

6.2 – France is testing due to a UK (or FR) specific requirement

Note:

columns 6.2 - 6.5 refer to the legislation imposing that the test be carried out and

6.3 - UK is testing according to EC legislation 6.4 – Spain is testing due to a Hungarian requirement

not to the body which has issued the actual test method, guideline or protocol. a test required by French legislation and carried out in Belgium according to an

6.5 – Sweden is testing due to a US specific requirement

Example:

ISO protocol must be coded as a national (FR) legislative requirement and be

6.6 - Germany is testing due to a Czech requirement (also an EC requirement)

entered into column 6.2 in the tables submitted by Belgium.

Footnotes:

EC Member States: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden, United Kingdom

Member Countries of Council of Europe (non-EC): Albania, Andorra, Bulgaria, Croatia, Cyprus, Czech Rep., Estonia, Hungary, Iceland, Latvia, Liechtenstein, Lithuania, Malta, Moldova, Norway, Poland, Romania, Russia, San Marino, Slovakia, Slovenia, Switzerland, 'the former Yugoslav Rep. of Macedonia', Turkey, Ukraine

TABLE 7: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS

Types of tests versus species

	7.1		7.2		7.3	7.4	7.5	7.6	7.7	7.8	7.9	7.10	7.11	7.12	7.13
	Species		ub-acute toxicity t		Skin	Skin	Eye	Sub-	Carcino-	Develop-	Muta-	Repro-	Toxicity	Other	Total
			(including limit to	est)	irritation	sensitisatio	irritation	chronic and	genicity	mental	genicit	ductive	to aquatic		
						n		chronic toxicity		toxicity	у	toxicity	vertebra-		
								toxicity					tes not included		
													in other		
													columns		
		7.2.1.	7.2.2	7.2.3											
		LD50,	Other lethal	Non lethal											
		LC50	methods	clinical signs											
	2.01	100		methods										400	
7.a.	Mice	100	60	000	040	450		400			160			120	440
7.b.	Rats	6	285	222	218	159		100						25	1015
7.c.	Guinea-Pigs			4		80									84
7.d. 7.e.	Hamsters Other Rodents														0
7.e. 7.f.	Rabbits			43	16		88							12	159
	Cats			43	10		00							12	0
7.g. 7.h.	Dogs			6											6
7.ii.	Ferrets			0											0
7.i.	Other Carnivores														0
7.k.	Horses, donkeys and cross														0
/ .K.	breds														
7.1.	Pigs														0
7.m.	Goats														0
7.n.	Sheep														0
7.o.	Cattle														0
7.p.	Prosimians														0
7.q.	New World Monkeys														0
7.r.	Old World Monkeys														0
7.s.	Apes														0
7.t.	Other Mammals														0
7.u.	Quail														0
7.v.	Other birds														0
7.w.	Reptiles														0
7.x.	Amphibians														0
7.y.	Fish														0
7.z.	TOTAL	106	345	275	234	239	88	100	0	0	160	0	0	157	1704

TABLE 8: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS

Types of tests versus products

	8.1 Products		8.2 nd sub-acute tox ods (including li		8.3 Skin irritation	8.4 Skin sensitisatio n	8.5 Eye irritation	8.6 Sub- chronic and chronic toxicity	8.7 Carcino genicity	8.8 Develop- mental toxicity	8.9 Muta- genicit y	8.10 Reproductive toxicity	8.11 Toxicity to aquatic vertebra- tes not included in other columns	8.12 Other	8.13 Total
		8.2.1. LD50, LC50	8.2.2 Other lethal methods	8.2.3 Non lethal clinical signs methods											
8.a.	Products/substances or devices for human medicine and dentistry and for veterinary medicine	50	320	89	11	80					160			12	722
8.b.	Products/substances used or intended to be used mainly in agriculture	50	25	8	46	14	19							19	181
8.c.	Products/substances used or intended to be used mainly in industry			124	147	145	69	100						120	705
8.d.	Products/substances used or intended to be used mainly in the household														0
8.e.	Products/substances used or intended to be used mainly as cosmetics or toiletries														0
8.f.	Products/substances used or intended to be used mainly as additives in food for human consumption	6													6
8.g.	Products/substances used or intended to be used mainly as additives in food for animal consumption			54	30										84
8.h.	Potential or actual contaminants in the general environment which do not appear in other columns														0
8.i.	Other toxicological or safety evaluations													6	6
8.j.	TOTAL	106	345	275	234	239	88	100	0	0	160	0	0	157	1704

SWEDEN

Statistical data submitted

The statistical data have been submitted by the National Board for Laboratory Animals.

Comments of Swedish authorities

Additional comments and remarks on the Swedish statistical records over used laboratory animals 2005.

The deadline for submitting the statistical records covering the use of laboratory animals during 2005 to the EU commission was in July 2006. Most researchers were prompt and submitted their reports in March, although some were as late as May-June despite several reminders from the Swedish Animal Welfare Agency (SAWA).

Electronical statistical form and database

During 2006 SAWA has developed an electronically statistical reporting form that will give the researcher a possibility to submit the statistical records electronically to a computer base. SAWA's goal is that this will make it easier for the researcher to submit the statistical records and also that it will give the authority an excellent opportunity to handle, analyze and present the statistical records more easily.

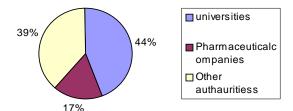
86/609/EEC Directive

According to the EU definition (directive 86/609/EEC) the number of laboratory animals used during 2005 in Sweden reached about 505 600. This is approx. a 12 % increase (about 58 000 animals) compared to 2004. Three kinds of animals were predominately used in animal experimentation, the mice, the rat and fish. Indeed, these three groups comprised about 90 % of all laboratory animals used during 2005. The increase in the use of mice is probably due to increased use of genetically modified animals. The large number of fish used is mainly explained by tagging of fish in assessment studies. The increase in the use of mice as a laboratory animal is an ongoing trend that has been consistent during the last 10 year period.

Whereas, a clear decrease can be seen in the use of guinea pigs and rabbits throughout the 1990s, this may be due to new techniques of producing antibodies, using *in vitro* production instead of whole animals.

Diagram 1.

Illustrating the use of laboratory animals in Sweden during 2005 according to the EU directive. Sorted in different reporting categories.



Specific use of animals

As in previous years most laboratory animals were used in either fundamental biological research (43%) or in development of product/devices (17%) used in human or veterinary medicine. During 2005, 3% of the animals were used in toxicological research, and finally, less than 1% of the total numbers of laboratory animals were used for diagnosing diseases. The most common animals used in toxicological research are mice, rats and fish and to lesser extent dogs and rabbits. Mammals were mostly used in experiments concerning products/substances or devices relating to human medicine, dentistry and veterinary medicine, fish are mainly used in the evaluation of hazardous environmental substances.

Reused animals

During 2005, 209 animals were reused in experiments according to the EU directive. This is a slight increase compared to 2004 when 168 animals were reused. Of the animals reused approx. 90 % were dogs (150 animals). To a much lesser extent old world monkeys and rabbits were reused, 28 and 31 respectively.

Tendencies in Sweden

From 1990 until 2002 the mean number of laboratory animals used in Sweden was about 315 000 with the highest number 1994 (approx. 351 000) and the lowest 1997 (267 000). From 2003-2005 there has been a large increase in the number of animals used. This is mainly due to the fact that tagging of fish for assessment studies has been included as an animal experiment. After discussions with the Swedish Board of Fisheries, SAWA decided to include tagging of fish as an animal experiment. The mean number during 2003-2005 is about 489 000 animals where the mean number of tagged fish is approx. 160 000.

The reasons behind these fluctuations during the last decade are hard to speculate about. It may just be due to natural fluctuations and/or reflect the status of high or low economy in Sweden. However, one clear tendency is the decrease of rats throughout the 1990s. In 1990 approx. 160 000 rats were used according to the EU directive. Whereas, during the year 2005 the number of rats in experiments is down to 83 000, an almost 50 % decrease. On the other hand, the use of mice as laboratory animals has

increased throughout the 1990s; this rise is probably due to the increased use of transgenic technique(s).

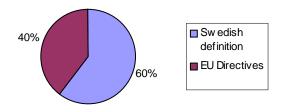
Swedish definition

Apart from the information, Sweden also collects its own statistical data on other use of laboratory animals. According to Swedish legislation all use of animals, which have a scientific purpose, should be recorded. Therefore, this statistical data includes all animals used in behaviour studies, feeding trials or animals being euthanized for the use of their tissues and organs. During 2005 about 767 000 animals were reported according to this definition. The dominating animals were bird, mice, rats, fish and pigs. This is an increase with nearly 208 000 animals compared with the figures in the year 2004 and is mainly due to increased use of birds and fish. The increase in birds is due to a large behavioural study on hens and the use of roosters, i.e. comb from roosters for the production of hyaloronic acids. The reason behind the increase in fish is that the Swedish Board of Fisheries performed a large feeding study with the goal of increasing the survival of fish released from hatcheries.

Fish assessment

Apart from the categories described above, Sweden also collects statistical records on fish used in assessment studies. That is fish that are caught by trawling, netting etc. During 2005 the number of fish in this category was approx. 6 356 000

Diagram 2. The use of laboratory animals in Sweden according to 86/609/EEC directive 40% (approx. 505 000) and the Swedish definition 60% (approx. 767 000)



Transgenic animals

The Swedish statistical records do not separate the use of transgenic animals from other laboratory animals. In agreement with EU directive, Sweden does not regard breeding of transgenic stocks as an experiment in it self. However, it is regarded as an experiment when transgenic animals are used in experiments or when new transgenic strains are created.

Conclusions

The overall impression is that the use of laboratory animals according to the EU directive shows an increase when comparing the year 2005 with the numbers used during 2004. The effect(s) is most obviously when comparing the use of animals by the universities and other authorities. This is probably due to the fact that the new animal facilities where ready and in full operation during 2005 and of course the tagging of fish. During the same period the Swedish pharmaceutical industries also show a slight increase in the use of laboratory animals (approx: 7000 animals). The reason behind these fluctuations difficult speculate about it may just be a fact of natural fluctuations.

TABLE 1: NUMBER OF ANIMALS USED IN RELATION TO THEIR PLACE OF ORIGIN

Origin versus species

1.1	1.2	1.3	1.4	1.5	1.6	1.7
Species	Total	Animals coming from registered	Animals coming from	Animals coming from	Animals coming from	Re-used animals
		breeding or supplying	elsewhere in the EC	Member Countries of the	other origins	
		establishments within the reporting		Council of Europe which are		
		country		parties to the Convention ETS		
				123 (excluding EC Member		
1.a. Mice (Mus musculus)	213 727	152 004	58 954	States)	2 769	
,				0		
1.b. Rats (Rattus norvegicus)	83 321	51 536	31 692	0	93	
1.c. Guinea-Pigs (Cavia porcellus)	2 014	1 923	91	0	0	
1.d. Hamsters (Mesocricetus)	167	63	104	0	0	
1.e. Other Rodents (other Rodentia)	1 269					
1.f. Rabbits (Oryctolagus cuniculus)	2 112	1 690	422	0	0	28
1.g. Cats (Felis catus)	220	175	0	0	45	0
1.h. Dogs (Canis familiaris)	1 166	1 035	47	0	84	150
1.i. Ferrets (Mustela putorius furo)	47	47	0	0	0	0
1.j. Other Carnivores (other <i>Carnivora</i>)	163					
1.k. Horses, donkeys and cross breds (<i>Equidae</i>)	650					
1.1. Pigs (<i>Sus</i>)	2 722					_
1.m. Goats (Capra)	23					
1.n. Sheep (Ovis)	256					
1.o. Cattle (Bos)	727					
1.p. Prosimians (<i>Prosimia</i>)	0	0	0	0	0	0
1.q. New World Monkeys (Ceboidea)	12	12	0	0	0	0
1.r. Old World Monkeys (Cercopithecoidea)	63	1	18	0	44	31
1.s. Apes (Hominoidea)	0	0	0	0	0	0
1.t. Other Mammals (other <i>Mammalia</i>)	639					
1.u. Quail (Coturnix coturnix)	0	0	0	0	0	
1.v. Other birds (other <i>Aves</i>)	7 838					
1.w. Reptiles (Reptilia)	0					
1.x. Amphibians (Amphibia)	5 496					
1.y. Fish (Pisces)	183 049					
1.z. TOTAL	505 681					

Note 1: Column 1.5 concerns only those Member Countries of the Council of Europe which, at the beginning of the reporting period, are Parties to the Convention ETS 123. Thus an updated list of those countries has to be used when filling in this column.

Note 2: Only the white boxes need to be completed.

Note 3: The number of re-used animals in column 1.7 should be excluded from the total in the column 1.2

TABLE 2: NUMBER OF ANIMALS USED IN EXPERIMENTS FOR SELECTED PURPOSES

Purpose versus species

	2.1	2.2	2.3	2.4	2.5	2.6	2.7	2.8	2.9	2.10
	Species	Biological	Research and	Production and	Production and	Toxicological	Diagnosis of	Education and	Other	Total
		studies of a	development of	quality control of	quality control of	and other safety	disease	training		
		fundamenta	products and	products and	products and	evaluations				
		l nature	devices for human	devices for	devices for	(including				
			medicine and	human medicine	veterinary	safety				
			dentistry and for	and dentistry	medicine	evaluation of				
			veterinary			products and				
			medicine			devices for				
			(excluding toxicological and			human medicine and				
			other safety			dentistry and				
			evaluations			for veterinary				
			counted in column			medicine)				
			2.6)			meareme)				
2.a.	Mice	152 796	54 941	68	54	2 246	65	1 128	2 429	213 727
2.b.	Rats	47 396	30 220	80	0	4 460	0	943	222	83 321
2.c.	Guinea-Pigs	578	956	443	17	0	0	6	14	2 014
2.d.	Hamsters	53	104	0	0	0	0	10	0	167
2.e.	Other Rodents	401	868	0	0	0	0	0	0	1 269
2.f.	Rabbits	1 053	472	46	2	347	2	35	155	2 112
2.g.	Cats	138	9	0	0	0	51	0	22	220
2.h.	Dogs	370	317	0	0	441	15	3	20	1 166
2.i.	Ferrets	47	0	0	0	0	0	0	0	47
2.j.	Other Carnivores	71	0	0	0	0	0	0	92	163
2.k.	Horses, donkeys and cross	13	0	0	0	0	7	570	60	650
	breds									
2.1.	Pigs	1 495	241	0	0	0	260	375	351	2 722
2.m.	Goats	0	0	0	0	0	0	0	23	23
2.n.	Sheep	132	27	0	0	0	0	1	96	256
2.0.	Cattle	315	33	0	0	0	29	340	10	727
2.p.	Prosimians	0	0	0	0	0	0	0	0	0
2.q.	New World Monkeys	0	0	0	0	12	0	0	0	12
2.r.	Old World Monkeys	52	11	0	0	0	0	0	0	63
2.s.	Apes	0	0	0	0	0	0	0	0	0
2.t.	Other Mammals	489	0	0	0	0	0	0	150	639
2.u.	Quail	0	0	0	0	0	0	0	0	0
2.v.	Other birds	5 689	245	15	0	0	0	1 011	878	7 838
2.w.	Reptiles	0	0	0	0	0	0	0	0	0
2.x.	Amphibians	5 419	77	0	0	0	0	0	0	5 496
2.y.	Fish	3 146	0	0	0	8 667	0	577	170 659	183 049
2.z.	TOTAL	219 653	88 521	652	73	16 173	429	4 999	175 181	505 681

TABLE 3: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS

Products versus species

	3.1	3.2	3.3	3.4	3.5	3.6	3.7	3.8	3.9	3.10	3.11
	Species	Products/	Products/	Products/	Products/	Products/	Products/	Products/	Potential or	Other toxico-	Total
	1	substances or	substances	substances	substances	substances	substances	substances	actual contami-	logical or	
		devices for	used or	used or	used or	used or	used or	used or	nants in the	safety	
		human	intended to	intended to	intended to	intended to	intended to be	intended to be	general envi-	evaluations	
		medicine and	be used	be used	be used	be used	used mainly	used mainly	ronment which		
		dentistry and	mainly in	mainly in	mainly in	mainly as	as additives in	as additives in	do not appear in		
		for veterinary	agriculture	industry	the	cosmetics	food for	food for	other columns		
		medicine			household	or toiletries	human	animal			
							consumption	consumption			
3.a.	Mice	1 042	0	0	0	0	0	0	159	1 045	2 246
3.b.	Rats	4 460	0	0	0	0	0	0	0	0	4 460
3.c.	Guinea-Pigs										0
3.d.	Hamsters										0
3.e.	Other Rodents										0
3.f.	Rabbits	347	0	0	0	0	0	0	0	0	347
3.g.	Cats										0
3.h.	Dogs	441	0	0	0	0	0	0	0	0	441
3.i.	Ferrets										0
3.j.	Other Carnivores										0
3.k.	Horses, donkeys and cross breds										0
3.1.	Pigs										0
3.m.	Goats										0
3.n.	Sheep										0
3.o.	Cattle										0
3.p.	Prosimians										0
3.q.	New World Monkeys	12	0	0	0	0	0	0	0	0	12
3.r.	Old World Monkeys										0
3.s.	Apes										0
3.t.	Other Mammals										0
3.u.	Quail										0
3.v.	Other birds										0
3.w.	Reptiles										0
3.x.	Amphibians										0
3.y.	Fish	0	300	0	0	0	0	0	8 367	0	8 667
3.z.	TOTAL	6 302	300	0	0	0	0	0	8 526	1 045	16 173

TABLE 4: NUMBER OF ANIMALS USED IN EXPERIMENTS FOR STUDIES ON HUMAN AND ANIMAL DISEASES

Main categories versus species

	4.1	4.2	4.3	4.4	4.5	4.6	4.7
	Species	Human cardiovascular	Human nervous and	Human cancer (excluding	Other human diseases	Studies specific to animal	Total
		diseases	mental disorders	evaluations of carcinogenic		diseases	
				hazards or risks)			
4.a.	Mice	33 843	27 196	30 212	81 523	19 919	192 693
4.b.	Rats	2 877	6 771	27 216	39 155	0	76 019
4.c.	Guinea-Pigs	0	344	485	760	17	1 606
4.d.	Hamsters	0	66	0	91	0	157
4.e.	Other Rodents	0	77	0	1 192	0	1 269
4.f.	Rabbits	22	373	115	900	2	1 412
4.g.	Cats	0	0	52	0	145	197
4.h.	Dogs	0	128	18	145	392	683
4.i.	Ferrets	0	0	33	14	0	47
4.j.	Other Carnivores	0	0	0	0	0	0
4.k.	Horses, donkeys and cross breds	0	0	0	0	0	0
4.1.	Pigs	0	534	0	978	370	1 882
4.m.	Goats	0	0	0	0	0	0
4.n.	Sheep	17	0	0	40	0	57
4.o.	Cattle	0	10	0	0	358	368
4.p.	Prosimians	0	0	0	0	0	0
4.q.	New World Monkeys	0	0	0	0	0	0
4.r.	Old World Monkeys	0	1	0	56	0	57
4.s.	Apes	0	0	0	0	0	0
4.t.	Other Mammals	0	0	0	0	0	0
4.u.	Quail	0	0	0	0	0	0
4.v.	Other birds	0	0	0	80	545	625
4.w.	Reptiles	0	0	0	0	0	0
4.x.	Amphibians	0	30	87	0	0	117
4.y.	Fish	0	0	0	1 020	1 000	2 020
4.z.	TOTAL	36 759	35 530	58 218	125 954	22 748	279 209

TABLE 5: NUMBER OF ANIMALS USED IN PRODUCTION AND QUALITY CONTROL OF PRODUCTS AND DEVICES FOR HUMAN MEDICINE AND DENTISTRY AND FOR VETERINARY MEDICINE

Regulatory requirements versus species

	5.1 Species	5.2 National legislation specific to a single EC Member State 1)	5.3 EC legislation including European Pharmacopoeia (requirements)	5.4 Member Country of Council of Europe (but not EC) legislation 2)	5.5 Other legislation	5.6 Any combination of 5.2/ 5.3/ 5.4/ 5.5	5.7 No regulatory requirements	5.8 Total
5.a.	Mice					68	54	122
5.b.	Rats		80					80
5.c.	Guinea-Pigs					406	54	460
5.d.	Hamsters							0
5.e.	Other Rodents							0
5.f.	Rabbits					42	6	48
5.g.	Cats							0
5.h.	Dogs							0
5.i.	Ferrets							0
5.j.	Other Carnivores							0
5.k.	Horses, donkeys and cross breds							0
5.1.	Pigs							0
5.m.	Goats							0
5.n.	Sheep							0
5.o.	Cattle							0
5.p.	Prosimians							0
5.q.	New World Monkeys							0
5.r.	Old World Monkeys							0
5.s.	Apes							0
5.t.	Other Mammals							0
5.u.	Quail							0
5.v.	Other birds						15	15
5.w.	Reptiles						_	0
5.x.	Amphibians							0
5.y.	Fish							0
5.z.	TOTAL	0	80	0	0	516	129	725

Examples:

5.2 – France is testing due to a UK (or FR) specific requirement

5.3 - UK is testing according to EC legislation

5.4 – Spain is testing due to a Hungarian requirement

5.5 – Sweden is testing due to a US specific requirement

5.6 - Germany is testing due to a Czech requirement (also an EC requirement)

Note:

columns 5.2 - 5.5 refer to the legislation imposing that the test be carried out and

not to the body which has issued the actual test method, guideline or protocol.

a test required by French legislation and carried out in Belgium according to an Example:

ISO protocol must be coded as a national (FR) legislative requirement and be

entered into column 5.2 in the tables submitted by Belgium.

Footnotes:

EC Member States: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden, United Kingdom

Member Countries of Council of Europe (non-EC): Albania, Andorra, Bulgaria, Croatia, Cyprus, Czech Rep., Estonia, Hungary, Iceland, Latvia, Liechtenstein, Lithuania, Malta, Moldova, Norway, Poland, Romania, Russia, San Marino, Slovakia, Slovenia, Switzerland, 'the former Yugoslav Rep. of Macedonia', Turkey, Ukraine

NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS TABLE 6:

Regulatory requirements versus species

	6.1	6.2	6.3	6.4	6.5	6.6	6.7	6.8
	Species	National legislation	EC legislation	Member Country of Council	Other legislation	Any combination of	No regulatory	Total
		specific to a single EC	including European	of Europe (but not EC)	-	6.2/ 6.3/ 6.4/ 6.5	requirements	
		Member State	Pharmacopoeia	legislation				
		1)	(requirements)	2)				
6.a.	Mice	842					1 404	2 246
6.b.	Rats	4 460						4 460
6.c.	Guinea-Pigs							
6.d.	Hamsters							
6.e.	Other Rodents							
6.f.	Rabbits	347						347
6.g.	Cats							
6.h.	Dogs	441						441
6.i.	Ferrets							
6.j.	Other Carnivores							
6.k.	Horses, donkeys and cross breds							
6.1.	Pigs							
6.m.	Goats							
6.n.	Sheep							
6.o.	Cattle							
6.p.	Prosimians							
6.q.	New World Monkeys					12		
6.r.	Old World Monkeys							
6.s.	Apes							
6.t.	Other Mammals							
6.u.	Quail							
6.v.	Other birds							
6.w.	Reptiles							
6.x.	Amphibians							
6.y.	Fish	7 510					1 157	8 667
6.z.	TOTAL	13 600				12	2 561	16 173

Examples:

6.2 – France is testing due to a UK (or FR) specific requirement

6.3 - UK is testing according to EC legislation

6.4 – Spain is testing due to a Hungarian requirement

6.5 – Sweden is testing due to a US specific requirement

6.6 - Germany is testing due to a Czech requirement (also an EC

requirement)

Note: columns 6.2 - 6.5 refer to the legislation imposing that the test be carried out and

not to the body which has issued the actual test method, guideline or protocol.

a test required by French legislation and carried out in Belgium according to an

ISO protocol must be coded as a national (FR) legislative requirement and be

entered into column 6.2 in the tables submitted by Belgium.

Footnotes: EC Member States: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden, United Kingdom

Example:

Member Countries of Council of Europe (non-EC): Albania, Andorra, Bulgaria, Croatia, Cyprus, Czech Rep., Estonia, Hungary, Iceland, Latvia, Liechtenstein, Lithuania, Malta, Moldova, Norway, Poland, Romania, Russia, San Marino, Slovakia, Slovenia, Switzerland, 'the former Yugoslav Rep. of Macedonia', Turkey, Ukraine

TABLE 7: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS

Types of tests versus species

		1						7.6				7.10		7.10	7.12
	7.1		7.2		7.3	7.4	7.5	7.6	7.7	7.8	7.9	7.10	7.11	7.12	7.13
	Species	Acute and s	sub-acute toxicity		Skin	Skin	Eye	Sub-	Carcino-	Develop-	Muta-	Repro-	Toxicity	Other	Total
			(including limit to	est)	irritation	sensitisatio n	irritation	chronic and chronic	genicity	mental toxicity	genicit y	ductive toxicity	to aquatic vertebra-		.
						11		toxicity		toxicity	y	toxicity	tes not		.
								toxicity					included		ı
													in other		1
													columns		1
		7.2.1.	7.2.2	7.2.3											1
		LD50,	Other lethal	Non lethal											ı
		LC50	methods	clinical signs											.
				methods											
7.a.				462		1 045		35	200		165			339	2 246
7.b.	Rats		265	3 229				113		165	405	51		232	4 460
7.c.	Guinea-Pigs														<u> </u>
7.d.	Hamsters														<u> </u>
7.e.	Other Rodents														<u> </u>
7.f.	Rabbits			36						263		48			347
7.g.	Cats														
7.h.	Dogs			383				40						18	441
7.i.	Ferrets														
7.j.	Other Carnivores														<u> </u>
7.k.	Horses, donkeys and cross														1
	breds														<u> </u>
7.1.	Pigs														<u> </u>
7.m.	Goats														
7.n.	Sheep														
7.0.	Cattle														
7.p.	Prosimians							4.0							
7.q.	New World Monkeys							12							
7.r.	Old World Monkeys														
7.s.	Apes	ļ													
7.t.	Other Mammals		<u> </u>												
7.u.	Quail	ļ													
7.v.	Other birds	ļ													
7.w.	Reptiles	-	1												
7.x.	Amphibians	ļ								0.570		0.050	0.440	405	0.007
7.y.	Fish			44.5	_	4.0	_	255	0.00	3 570		2 850	2 112	135	8 667
7.z.	TOTAL	0	265	4 110	0	1 045	0	200	200	3 998	570	2 949	2 112	724	16 173

TABLE 8: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS

Types of tests versus products

	8.1 Products		8.2 nd sub-acute toxi ods (including li		8.3 Skin irritation	8.4 Skin sensitisatio n	8.5 Eye irritation	8.6 Sub- chronic and chronic toxicity	8.7 Carcino genicity	8.8 Develop- mental toxicity	8.9 Muta- genicit y	8.10 Reproductive toxicity	8.11 Toxicity to aquatic vertebra- tes not included	8.12 Other	8.13 Total
		8.2.1. LD50, LC50	8.2.2 Other lethal methods	8.2.3 Non lethal clinical signs methods				toxicity					in other columns		
8.a.	Products/substances or devices for human medicine and dentistry and for veterinary medicine		265	4 110				165	200	428	446	99		589	6 302
8.b.	Products/substances used or intended to be used mainly in agriculture											300			300
8.c.	Products/substances used or intended to be used mainly in industry														0
8.d.	Products/substances used or intended to be used mainly in the household														0
8.e.	Products/substances used or intended to be used mainly as cosmetics or toiletries														0
8.f.	Products/substances used or intended to be used mainly as additives in food for human consumption											1 045			1 045
8.g.	Products/substances used or intended to be used mainly as additives in food for animal consumption														0
8.h.	Potential or actual contaminants in the general environment which do not appear in other columns							35		3 570	124	2 550	2 112	135	8 526
8.i.	Other toxicological or safety evaluations														0
8.j.	TOTAL	0	265	4 110	0	0	0	200	200	3 998	570	3 994	2 112	724	16 173

UNITED KINGDOM

Statistical data submitted

The United Kingdom statistical data for 2005 were prepared, quality assured and submitted by the "Home Office".

Within the United Kingdom (UK), Great Britain (GB) and Northern Ireland (NI) publish separate, annual statistical reports based largely on the number of procedures started rather than numbers of animals used. The 2005 data collection process was 100% complete.

In accord with our established practice the UK figures presented here have been recompiled from the original data in terms of animal numbers for the classes of animal use recorded in the EU statistical tables. It should be noted that the UK also regulates, and the UK domestic statistical reports enumerate, animals bred for the maintenance of colonies of genetically modified or harmful mutant animals, and that category of animal use largely accounts for the differences in the figures in the original GB & NI publications and those in this EU report.

Comments of United Kingdom authorities

In the UK, just over 1.87 million animals were used for the first time in procedures started in 2005, a rise of 57,000 on the number reported for 2002.

1,463,565 (78%) of the animals used were mice and rats.

Cold-blooded animals (fish, amphibia, and reptiles) accounted for 203,173 animals, 11% of the animals used.

Cats, dogs, equidae and non-human primates are accorded special protection in the UK and collectively amounted to 9,104 animals, 0.5% of the animals used - a reduction of 841 compared with 2002.

Non-human primates accounted for 3,115 animals, 0.16% of animals used – 58 fewer than in 2002.

99% of the animals that must be sourced from approved breeders or suppliers originated from UK registered breeding or supplying establishments. Less than 0.5% were sourced outside of EC or Council of Europe member countries.

974,046 animals (52%) were used for fundamental biological studies, research and development relating to human medicine, dentistry and veterinary medicine.

Toxicological or other safety evaluation used 248,610 animals (13%) – a reduction of 73,323 since 2002.

There was a marked reduction in the number of animals used to satisfy national legislation specific to a single member state, with the majority of the animal use (72%) being to fulfil multinational regulatory requirements.

110,384 animals (6%) were used for the production and quality control of products and devices for human medicine, dentistry or veterinary medicine – over 45,000 fewer than in 2002.

Approximately 40% of animals used received some form of anaesthesia. For the other animals the use of anaesthesia would have been deemed to increase the severity of the procedure.

As in 2002 no animals were used to evaluate the safety of either cosmetic products or cosmetic ingredients.

No animals were used in 2005 for monoclonal antibody production using the ascites method.

TABLE 1: NUMBER OF ANIMALS USED IN RELATION TO THEIR PLACE OF ORIGIN

Origin versus species

1.1	1.2	1.3	1.4	1.5	1.6	1.7
Species	Total	Animals coming from	Animals coming from	Animals coming from	Animals coming from	Re-used animals
		registered breeding or supplying	elsewhere in the EC	Member Countries of the	other origins	
		establishments within the		Council of Europe which are		
		reporting country		parties to the Convention ETS		
				123 (excluding EC Member		
		4 2 4 2 2 2 2		States)	2 222	
1.a. Mice (Mus musculus)	1 052 064	1 048 052	690	40	3 282	
1.b. Rats (Rattus norvegicus)	411 501	408 104	1 183	-	2 214	
1.c. Guinea-Pigs (Cavia porcellus)	28 918	28 918	-	-	-	
1.d. Hamsters (Mesocricetus)	3 746	2 219	1 256	271	-	
1.e. Other Rodents (other <i>Rodentia</i>)	8 216					
1.f. Rabbits (Oryctolagus cuniculus)	15 523	15 063	410	2	48	2 315
1.g. Cats (Felis catus)	308	205	103	-	-	175
1.h. Dogs (Canis familiaris)	5 373	4 294	194	-	885	907
1.i. Ferrets (Mustela putorius furo)	1 004	970	-	-	34	18
1.j. Other Carnivores (other <i>Carnivora</i>)	938					
1.k. Horses, donkeys and cross breds (Equidae)	308					
1.1. Pigs (<i>Sus</i>)	4 127					
1.m. Goats (Capra)	274					
1.n. Sheep (Ovis)	11 772					
1.o. Cattle (Bos)	6 306					
1.p. Prosimians (<i>Prosimia</i>)	=	1	Ī	-	-	=
1.q. New World Monkeys (Ceboidea)	643	501	108	34	-	148
1.r. Old World Monkeys (Cercopithecoidea)	2 472	135	6	-	2 331	590
1.s. Apes (Hominoidea)	-	-	-	-	-	-
1.t. Other Mammals(other <i>Mammalia</i>)	2 541					
1.u. Quail (Coturnix coturnix)	140	140	-	-	-	
1.v. Other birds (other <i>Aves</i>)	114 860					
1.w. Reptiles (<i>Reptilia</i>)	84					
1.x. Amphibians (Amphibia)	10 585					
1.y. Fish (Pisces)	192 504					
1.z. TOTAL	1 874 207					

Note 1: Column 1.5 concerns only those Member Countries of the Council of Europe which, at the beginning of the reporting period, are Parties to the Convention ETS 123. Thus an updated list of those countries has to be used when filling in this column.

Note 2: Only the white boxes need to be completed.

Note 3: The number of re-used animals in column 1.7 should be excluded from the total in the column 1.2

TABLE 2: NUMBER OF ANIMALS USED IN EXPERIMENTS FOR SELECTED PURPOSES

Purpose versus species

	1 ur pose versus species												
	2.1	2.2	2.3	2.4	2.5	2.6	2.7	2.8	2.9	2.10			
	Species	Biological	Research and	Production and	Production and	Toxicological	Diagnosis of	Education and	Other	Total			
		studies of a	development of	quality control of	quality control of	and other safety	disease	training					
		fundamenta	products and	products and	products and	evaluations							
		1 nature	devices for human	devices for	devices for	(including							
			medicine and	human medicine	veterinary	safety							
			dentistry and for	and dentistry	medicine	evaluation of							
			veterinary			products and							
			medicine			devices for							
			(excluding			human							
			toxicological and			medicine and							
			other safety			dentistry and							
			evaluations			for veterinary							
			counted in column			medicine)							
2.0	Mice	55 660	2.6) 92 488	63 461	18 280	81 113	8 016	896	432 150	1 052 064			
2.a. 2.b.	Rats	115 092	143 212	4 061	10 200	110 005	10	1 427	37 694	411 501			
2.c.	Guinea-Pigs	3 235	11 578	7 396	1 273	2 890	448	118	1 980	28 918			
2.d.	Hamsters	1 656	30	60	480	1 304	440	- 110	216	3 746			
2.d. 2.e.	Other Rodents	5 266	2 794	00	400	40	_	2	114	8 216			
2.e. 2.f.	Rabbits	1 488	768	338	990	8 456	1 737	32	1 714	15 523			
	Cats	237	71	330	990	0 430	1 131	32	1 / 14	308			
2.g. 2.h.	Dogs	119	748	4	-	4 248	15	-	39	5 373			
2.n. 2.i.	Ferrets					4 248				1 004			
	Other Carnivores	172 502	94	6	-	-	35	13	684 436	938			
2.j. 2.k.		38	- 04	-	50	-	-	-		308			
2.K.	Horses, donkeys and cross breds	38	31	-	50	25	68	8	88	308			
2.1.	Pigs	2 046	445	36	716	541	_	-	343	4 127			
2.m.	Goats	233	6		- 10	3	11	-	21	274			
2.m.	Sheep	5 681	136	-	169	223	408	5	5 150	11 772			
2.0.	Cattle	4 312	523	-	718	345	9	-	399	6 306			
2.p.	Prosimians	-	-	-	-	-	-	-	-	-			
2.g.	New World Monkeys	114	86	8	-	334	16	-	85	643			
2.r.	Old World Monkeys	89	110	-	_	2 257		-	16	2 472			
2.s.	Apes	-	-	-	-		-	-	- 1				
2.t.	Other Mammals	1 937	-	-	-	15	-	-	589	2 541			
2.u.	Ouail	140	-	-	_	-	-	-	-	140			
2.v.	Other birds	29 119	687	-	5 746	4 000	2 470	6	72 832	114 860			
2.w.	Reptiles	70	-	-	-	12	-	-	2	84			
2.x.	Amphibians	8 943	-	-	-	-	-	-	1 642	10 585			
2.y.	Fish	106 445	2 275	-	6 592	32 799	163	-	44 230	192 504			
2.z.	TOTAL	642 594	256 082	75 370	35 014	248 610	13 406	2 507	600624	1 874 207			

TABLE 3: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS

Products versus species

	3.1	3.2	3.3	3.4	3.5	3.6	3.7	3.8	3.9	3.10	3.11
	Species	Products/	Products/	Products/	Products/	Products/	Products/	Products/	Potential or	Other toxico-	Total
		substances or	substances	substances	substances	substances	substances	substances	actual contami-	logical or	
		devices for	used or	used or	used or	used or	used or	used or	nants in the	safety	
		human	intended to	intended to	intended to	intended to	intended to be	intended to be	general envi-	evaluations	
		medicine and	be used	be used	be used	be used	used mainly	used mainly	ronment which		
		dentistry and	mainly in	mainly in	mainly in	mainly as	as additives in	as additives in	do not appear in		
		for veterinary	agriculture	industry	the	cosmetics	food for	food for	other columns		
		medicine			household	or toiletries	human	animal			
							consumption	consumption			
3.a.	Mice	49965	3335	6955	21	-	-	-	3	20834	81113
3.b.	Rats	70890	18134	10621	-	-	-	-	324	10036	110005
3.c.	Guinea-Pigs	2366	120	128	-	-	-	-	-	276	2890
3.d.	Hamsters	721	551	16	-	-	-	-	•	16	1304
3.e.	Other Rodents	-	40	-	-	-	-	-	-	-	40
3.f.	Rabbits	5378	1120	1742	-	-	-	-	-	216	8456
3.g.	Cats	-	-	-	-	-	-	-	1	-	-
3.h.	Dogs	4012	91	3	-	-	-	-	1	142	4248
3.i.	Ferrets	-	-	-	-	-	-	-	1	-	-
3.j.	Other Carnivores	-	-	-	-	-	-	-	-	-	
3.k.	Horses, donkeys and cross breds	25	-		-	-	-	-	=	-	25
3.1.	Pigs	409	90	-	-	-	-	-	-	42	541
3.m.	Goats	-	3	-	_	_	-	-	-	-	3
3.n.	Sheep	213	10	-	_	_	-	-	-	-	223
3.o.	Cattle	297	48	-	-	_	-	-	-	_	345
3.p.	Prosimians	-	-	-	-	-	-	-	-	_	-
3.q.	New World Monkeys	297	-	-	-	-	-	-	-	37	334
3.r.	Old World Monkeys	1961	-	-	-	-	-	-	-	296	2257
3.s.	Apes	-	-	-	-	-	-	-	-	-	-
3.t.	Other Mammals	15	-	-	-	-	-	-	-	-	15
3.u.	Quail	-	-	-	-	-	-	-	-	-	-
3.v.	Other birds	1240	2620	-	_	-	-	-	131	9	4000
3.w.	Reptiles	-	-	-	-	-	-	-	-	12	12
3.x.	Amphibians	-	-	-	-	-	-	-	-	-	-
3.y.	Fish	3326	6579	4398	-	-	-	-	16109	2387	32799
3.z.	TOTAL	141115	32741	23863	21	-	-	-	16567	34303	248610

TABLE 4: NUMBER OF ANIMALS USED IN EXPERIMENTS FOR STUDIES ON HUMAN AND ANIMAL DISEASES

Main categories versus species

	4.1	4.2	4.3	4.4	4.5	4.6	4.7
	Species	Human cardiovascular	Human nervous and	Human cancer (excluding	Other human diseases	Studies specific to animal	Total
		diseases	mental disorders	evaluations of carcinogenic		diseases	
				hazards or risks)			
4.a.	Mice	22260	99729	86802	459327	22392	690510
4.b.	Rats	16176	145474	5694	187929	1464	356737
4.c.	Guinea-Pigs	975	1884	-	23963	1564	28386
4.d.	Hamsters	-	740	76	1707	639	3162
4.e.	Other Rodents	38	4517	85	3470	-	8110
4.f.	Rabbits	1005	99	63	9944	1337	12448
4.g.	Cats	-	98	-	139	71	308
4.h.	Dogs	466	3	10	4502	280	5261
4.i.	Ferrets	102	140	-	749	-	991
4.j.	Other Carnivores	2	ı	-	500	403	905
4.k.	Horses, donkeys and cross breds	-	12	-	94	192	298
4.1.	Pigs	278	62	-	2205	1543	4088
4.m.	Goats	31	ī	-	232	8	271
4.n.	Sheep	116	474	-	6244	4864	11698
4.o.	Cattle	135	1788	-	2398	1914	6235
4.p.	Prosimians	1	ı	-	-	-	-
4.q.	New World Monkeys	33	50	-	547	-	630
4.r.	Old World Monkeys	41	76	-	2097	-	2214
4.s.	Apes	-	-	-	-	-	-
4.t.	Other Mammals	240	182	-	1697	15	2134
4.u.	Quail	-	140	-	-	-	140
4.v.	Other birds	1377	5456	-	25010	80509	112352
4.w.	Reptiles	-	70	-	12	-	82
4.x.	Amphibians	472	53	745	7673	-	8943
4.y.	Fish	-	3282	-	105746	25538	134566
4.z.	TOTAL	43747	264329	93475	846185	142733	1390469

TABLE 5: NUMBER OF ANIMALS USED IN PRODUCTION AND QUALITY CONTROL OF PRODUCTS AND DEVICES FOR HUMAN MEDICINE AND DENTISTRY AND FOR VETERINARY MEDICINE

Regulatory requirements versus species

		1		equiterness versus s				
	5.1	5.2	5.3	5.4	5.5	5.6	5.7	5.8
	Species	National legislation	EC legislation	Member Country of Council	Other legislation	Any combination of	No regulatory	Total
	-	specific to a single EC	including European	of Europe (but not EC)		5.2/ 5.3/ 5.4/ 5.5	requirements	
		Member State	Pharmacopoeia	legislation			•	
		1)	(requirements)	2)				
5.a.	Mice	1924	6000	-	136	66574	7107	81741
5.b.	Rats	-	1920	-	-	567	1574	4061
5.c.	Guinea-Pigs	5711	1399	-	122	1137	300	8669
5.d.	Hamsters	-	480	-	-	-	60	540
5.e.	Other Rodents	-	-	-	-	-	-	-
5.f.	Rabbits	116	-	-	-	1202	10	1328
5.g.	Cats	-	-	-	-	-	-	-
5.h.	Dogs	-	-	-	-	-	4	4
5.i.	Ferrets	-	-	-	=	-	6	6
5.j.	Other Carnivores	-	-	-	-	-	-	-
5.k.	Horses, donkeys and cross breds	-	-	-		50	-	50
5.1.	Pigs	24	716	-	=	-	12	752
5.m.	Goats	-	-	-	-	-	-	-
5.n.	Sheep	1	98	-	ı	71	-	169
5.0.	Cattle	49	265	-	-	352	52	718
5.p.	Prosimians	-	-	-	-	-	-	-
5.q.	New World Monkeys	-	-	-	-	-	8	8
5.r.	Old World Monkeys	-	-	-	-	-	-	-
5.s.	Apes	-	-	-	-	-	-	-
5.t.	Other Mammals	-	-	-	-	-	-	-
5.u.	Quail	-	-	=	-	-	-	-
5.v.	Other birds	-	68	-	-	5185	493	5746
5.w.	Reptiles	-	-	-	-	-	-	-
5.x.	Amphibians	-	-	-	-	-	-	-
5.y.	Fish	-	2621	-	-	3971	-	6592
5.z.	TOTAL	7824	13567	•	258	79109	9626	110384

Examples:

Footnotes:

5.2 – France is testing due to a UK (or FR) specific requirement

5.3 - UK is testing according to EC legislation

5.4 – Spain is testing due to a Hungarian requirement

5.5 – Sweden is testing due to a US specific requirement

5.6 - Germany is testing due to a Czech requirement (also an EC

requirement)

Note:

columns 5.2 - 5.5 refer to the legislation imposing that the test be carried out and

not to the body which has issued the actual test method, guideline or protocol.

a test required by French legislation and carried out in Belgium according to an Example:

ISO protocol must be coded as a national (FR) legislative requirement and be

entered into column 5.2 in the tables submitted by Belgium.

1) EC Member States: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden, United Kingdom

Member Countries of Council of Europe (non-EC): Albania, Andorra, Bulgaria, Croatia, Cyprus, Czech Rep., Estonia, Hungary, Iceland, Latvia, Liechtenstein, Lithuania, Malta, Moldova, Norway, Poland, Romania, Russia, San Marino, Slovakia, Slovenia, Switzerland, 'the former Yugoslav Rep. of Macedonia', Turkey, Ukraine

NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS

Regulatory requirements versus species

	6.1	6.2	6.3	6.4	6.5	6.6	6.7	6.8
	Species	National legislation	EC legislation	Member Country of Council	Other legislation	Any combination of	No regulatory	Total
	•	specific to a single EC	including European	of Europe (but not EC)	•	6.2/ 6.3/ 6.4/ 6.5	requirements	
		Member State	Pharmacopoeia	legislation			•	
		1)	(requirements)	2)				
6.a.	Mice	566	8683	-	1921	57004	12939	81113
6.b.	Rats	1000	3862	-	3869	92289	8985	110005
6.c.	Guinea-Pigs	4	165	-	256	2076	389	2890
6.d.	Hamsters	-	-	-	=	1022	282	1304
6.e.	Other Rodents	-	-	-	=	-	40	40
6.f.	Rabbits	29	2114	-	539	5662	112	8456
6.g.	Cats	-	-	-	-	-	-	-
6.h.	Dogs	-	24	-	-	4051	173	4248
6.i.	Ferrets	-	-	-	-	-	-	-
6.j.	Other Carnivores	-	-	-	=	-	=	-
6.k.	Horses, donkeys and cross breds	-	-	-	=	25	=	25
6.1.	Pigs	-	181	-	-	305	55	541
6.m.	Goats	-	-	-	-	3	-	3
6.n.	Sheep	-	36	-	=	181	6	223
6.o.	Cattle	4	151	-	-	178	12	345
6.p.	Prosimians	-	-	-	=	-	=	-
6.q.	New World Monkeys	-	-	-	-	297	37	334
6.r.	Old World Monkeys	-	-	-	-	2207	50	2257
6.s.	Apes	-	-	-	=	-	=	-
6.t.	Other Mammals	-	15	-	-	-	=	15
6.u.	Quail	-	-	-	-	-	=	-
6.v.	Other birds	50	950	-	522	2306	172	4000
6.w.	Reptiles	12	-	-	-	-	=	12
6.x.	Amphibians	-	-	-	-	-	-	-
6.y.	Fish	3581	7148	-	1144	15110	5816	32799
6.z.	TOTAL	5246	23329	-	8251	182716	29068	248610

Examples:

6.2 – France is testing due to a UK (or FR) specific requirement

6.3 - UK is testing according to EC legislation

6.4 – Spain is testing due to a Hungarian requirement

6.5 – Sweden is testing due to a US specific requirement

6.6 - Germany is testing due to a Czech requirement (also an EC

requirement)

Note:

Example:

columns 6.2 - 6.5 refer to the legislation imposing that the test be carried out and

not to the body which has issued the actual test method, guideline or protocol.

a test required by French legislation and carried out in Belgium according to an ISO protocol must be coded as a national (FR) legislative requirement and be

entered into column 6.2 in the tables submitted by Belgium.

Footnotes:

EC Member States: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden, United Kingdom

Member Countries of Council of Europe (non-EC): Albania, Andorra, Bulgaria, Croatia, Cyprus, Czech Rep., Estonia, Hungary, Iceland, Latvia, Liechtenstein, Lithuania, Malta, Moldova, Norway, Poland, Romania, Russia, San Marino, Slovakia, Slovenia, Switzerland, 'the former Yugoslav Rep. of Macedonia', Turkey, Ukraine

TABLE 7: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS

Types of tests versus species

	7.1 Species	7.2 Acute and sub-acute toxicity testing methods (including limit test) 7.2.1. 7.2.2 7.2.3 LD50, Other lethal Non lethal				7.4 Skin sensitisatio n	7.5 Eye irritation	7.6 Sub- chronic and chronic toxicity	7.7 Carcino- genicity	7.8 Develop- mental toxicity	7.9 Muta- genicit y	7.10 Reproductive toxicity	7.11 Toxicity to aquatic vertebra- tes not included in other columns	7.12 Other	7.13 Total
		LC50	methods	clinical signs methods											
7.a.	Mice	6784	384	7497	6	2496	-	4424	7549	769	3247	-	-	47957	81113
7.b.	Rats	3636	2309	30789	-	-	-	11778	8654	4556	5565	25216	-	17502	110005
7.c.	Guinea-Pigs	217	-	86	12	278	-	-	-	-	-	-	-	2297	2890
7.d.	Hamsters	-	-	482	-	-	-	-	-	-	-	-	-	822	1304
7.e.	Other Rodents	-	-	-	-	-	-	-	-	-	-	-	-	40	40
7.f.	Rabbits	-	12	532	1302	-	837	244	-	3141	-	123	-	2265	8456
7.g.	Cats	-	-	-	-	-	-	-	-	-	-	-	-	-	-
7.h.	Dogs	-	-	2279	-	-	-	1541	-	-	-	-	-	428	4248
7.i.	Ferrets	-	-	-	-	-	-	-	-	-	-	-	-	-	-
7.j.	Other Carnivores	-	-	-	-	-	-	-	-	-	-	-	-	-	-
7.k.	Horses, donkeys and cross breds	ı	-	1	-	-	-	ı	-	-	-	-	-	25	25
7.1.	Pigs	-	-	52	-	-	-	1	1	-	-	-	-	489	541
7.m.	Goats	-	-	1	-	-	-	1	-	-	-	-	-	3	3
7.n.	Sheep	-	-	24	-	-	-	-	-	-	-	-	-	199	223
7.o.	Cattle	-	-	39	-	-	-	-	-	-	-	-	-	306	345
7.p.	Prosimians	-	-	-	-	-	-	-	-	-	-	-	-	-	-
7.q.	New World Monkeys	-	13	112	-	-	-	155	-	-	-	-	-	54	334
7.r.	Old World Monkeys	-	-	1035	-	-	-	838	-	-	-	-	-	384	2257
7.s.	Apes	-	-	-	-	-	-	-	-	-	-	-	-	-	-
7.t.	Other Mammals	-	-	-	-	-	-	-	-	-	-	-	-	15	15
7.u.	Quail	-	-	-	-	-	-	-	-	-	-	-	-	-	-
7.v.	Other birds	920	140	400	-	-	-	-	-	-	-	-	-	2540	4000
7.w.	Reptiles	-	-	-	-	-	-	-	-	-	-	-	-	12	12
7.x.	Amphibians	- 0.466	-	-	-	-	-	-	-	-	-	-	-	-	-
7.y.	Fish	9192	7157	6963	-	-	-	752	-		226	710	-	7799	32799
7.z.	TOTAL	20749	10015	50290	1320	2774	837	19732	16203	8466	9038	26049	-	83137	248610

TABLE 8: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS

Types of tests versus products

	8.1 Products		8.2 and sub-acute toxi ods (including li 8.2.2 Other lethal methods		8.3 Skin irritation	8.4 Skin sensitisatio n	8.5 Eye irritation	8.6 Sub- chronic and chronic toxicity	8.7 Carcino genicity	8.8 Develop- mental toxicity	8.9 Muta- genicit y	8.10 Reproductive toxicity	8.11 Toxicity to aquatic vertebra- tes not included in other columns	8.12 Other	8.13 Total
8.a.	Products/substances or devices for human medicine and dentistry and for veterinary medicine	-	383	32535	103	428	18	16045	14662	7260	5558	14797	-	49326	141115
8.b.	Products/substances used or intended to be used mainly in agriculture	3213	2703	7461	280	365	240	2214	1377	832	839	7915	-	5302	32741
8.c.	Products/substances used or intended to be used mainly in industry	2288	1824	7050	937	1775	579	577	60	264	1720	2357	-	4432	23863
8.d.	Products/substances used or intended to be used mainly in the household	-	-	-	-	21	-	-	-	-	-	_	-	-	21
8.e.	Products/substances used or intended to be used mainly as cosmetics or toiletries	-	-	-	-	-	-	-	-	-	-	-	-	-	-
8.f.	Products/substances used or intended to be used mainly as additives in food for human consumption	-	-	-	-	-	-	-	-	-	-	-	-	-	-
8.g.	Products/substances used or intended to be used mainly as additives in food for animal consumption	-	-	-	-	-	-	-	-	-	-	-	-	-	-
8.h.	Potential or actual contaminants in the general environment which do not appear in other columns	4268	3927	2504	-	-	-	-	-	-	226	980	-	4662	16567
8.i.	Other toxicological or safety evaluations	10980	1178	740	-	185	-	896	104	110	695	-	-	19415	34303
8.j.	TOTAL	20749	10015	50290	1320	2774	837	19732	16203	8466	9038	26049	-	83137	248610